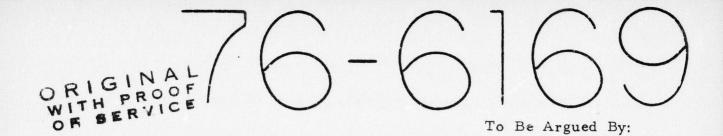
United States Court of Appeals for the Second Circuit



BRIEF FOR APPELLANT



UNITED STATES COURT OF APPEALS

for the

SECOND CIRCUIT

UNITED STATES OF AMERICA,

Plaintiff-Appellee,

JOSEPH H. EINSTEIN

-against-

NOVA SCOTIA FOOD PRODUCTS CORP., DAVID SKLAR and EMANUEL SKLAR,

Defendants-Appellants,

and

NATIONAL FISHERIES INSTITUTE,

Intervenor-Appellant.

On Appeal from a Judgment of the United States District Court for the Eastern District of New York

BRIEF OF APPELLANTS

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UNI	red s	STATES	COURT	OF	APPEALS
FOR	THE	SECOND	CIRC	JIT	

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UNITED STATES OF AMERICA,

Plaintiff-Appellee,

- against -

NOVA SCOTIA FOOD PRODUCTS CORP., DAVID SKLAR and EMANUEL SKLAR,

Defendants-Appellants,

- and -

NATIONAL FISHERIES INSTITUTE,

Intervenor-Appellant.

PRELIMINARY STATEMENT

This is an appeal from a final judgment of the United States District Court for the Eastern District of New York following a non-jury trial before Hon. John F. Dooling, Jr. The court below rendered an extensive written opinion which is reported at 417 F.Supp. 1364 (E.D.N.Y. 1976).

THE ISSUES PRESENTED FOR REVIEW

1. Are the time-temperature-salinity requirements of the regulation adopted by the Food and Drug Administration (FDA) as contained in 21 C.F.R. Part 128a in excess of the statutory authority upon which they are based, to wit, 21 U.S.C. 342(a)(4)?

- 2. Is the regulation invalid because of FDA's secret consideration of extensive scientific data of which the regulated persons were not advised and which they had no opportunity to rebut?
- 3. Is the regulation invalid because it is unsupported by the administrative record and because of FDA's failure to adequately set forth its basis and purpose?
- 4. Given the circumstances surrounding its adoption, does the regulation have the force and effect of law or is it merely interpretive?
- 5. Did the plaintiff prove the required elements necessary to sustain its claim for injunctive relief?
- 6. Does the injunction issued operate unfairly because it would destroy an entire industry, discriminates against defendants and fails to recognize the legitimate need for a reasonable delay prior to its becoming effective?

STATEMENT OF THE CASE

This action involves the continued existence of the smoked fish industry in the United States.* Enforcement of the regulation at bar will put an end to the hot-smoking of fish because it is impossible to comply with the regulation

^{*} The National Fisheries Institute, a broad based trade association, has intervened in this litigation because of the drastic adverse effect which enforcement of the regulation involved would have not only upon the smoked fish processors, but upon the entire industry (451-452; Motion To Intervene).

and produce a marketable product. FDA promulgated the regulation and insists upon its enforcement even though it is clear that no reasonable possibility of injury to public health exists as a result of current processing methods being utilized by industry.

We submit that there is no basis in law or fact for the destruction of a viable segment of our economy which, for many years, has produced a tasty, popular and totally safe product.

The government commenced this action to enjoin defendants from processing hot-smoked whitefish other than in accordance with certain regulations promulgated in 1970 (4-13).* These regulations are known as Good Manufacturing Practice (GMP) regulations. Following a three day bench trial, Hon. John F. Dooling issued an opinion (723-776) followed by a final judgment granting relief to the government (804-810).

Essentially, the court enjoined defendants from preparing whitefish unless they did so in compliance with the
time-temperature-salinity requirements of the GMP regulations
contained in 21 CFR 128a (810). This injunctive relief was
imposed even though the record clearly demonstrated that it
was impossible to comply with the regulation and still produce a marketable product, and even though there was no
reasonable possibility of injury to health as a result of
existing processing methods.

^{*} All numerical references are to the Joint Appendix.

The portions of the regulation at issue here, as enforced by the judgment below, set forth two alternative processing parameters for all hot-smoked fish.*

- 1. The fish must be brined to a level of 5.0% water-phase salt in the interior loin muscle and baccooked at a temperature of 150°F for 30 minutes; or
- 2. The fish must be brined to a level of 3.5% water-phase salt in the interior loin muscle and be cooked at a temperature of 180°F for 30 minutes.

As will be shown, these processing parameters cannot be met if there is to be a marketable product. It is clear that enforcement of the regulation in this regard will totally destroy an existing viable segment of our economy without any correlative benefit to public health or safety.

In a very significant sense this litigation and the regulation involve much ado about nothing. There was a great deal of discussion at the trial and in the government's presentation about the hazards of botulism and the GMP was supposedly adopted to deal with that potential danger to public health. However, the record clearly indicates that botulism is not truly an issue here.

Clostridium botulinum is a microorganism which is

^{*} The trial involved only whitefish and the final judgment deals only with whitefish. The regulations are broader in scope and apply to all hot-smoked fish.

found in the mud and sediment of bodies of water. During the course of their natural existence whitefish may come in contact with the organism which may adhere to the body of the whitefish or find its way into its intestinal tract. (525-528; Def't. Exh. "D", Administrative Record at Tab "B" and at Tab "F-63").

If processed whitefish is not refrigerated, the organism may grow and multiply. This outgrowth produces a toxin which can be injurious to health. (562, 574-481). But, this risk is highly theoretical and has not materialized in practice.

Between 1899 and 1964 there were only 651 reported outbreaks of botulism in the United States and Canada. Of these, only 65 related to commercially processed foods. Of these 65, only 8 were attributable to hot-smoked whitefish. In all 8 instances, vacuum packed whitefish was involved. (560-572, 702-706).*

These 8 outbreaks occurred in 1960 and 1963. The industry has abandoned vacuum packing (572) and there has not been a single case of botulism associated with commercially prepared whitefish since 1963 (451, 562). This fact must be weighed in light of the further fact that 2,750,000 pounds of whitefish are processed annually (451).

^{*} Vacuum packing creates special problems because it inhibits spoilage bacteria which might lead to consumer rejection of the product but such packaging does not inhibit botulinum outgrowth (574-575).

Thus, in the thirteen year period embracing 1964 through 1976, 37,500,000 pounds of whitefish have been commercially processed in the United States without a single reported case of botulism.

This is supposedly a case involving the potential danger of botulism. Yet the government did not even bother to test the whitefish collected at the defendant's plant for botulism (137). Dr. Eklund, a leading expert in the field and an employee of the National Marine Fisheries Service of the Department of Commerce (184-190), did test 79 samples of whitefish gathered from various processing plants, including defendants. He found not one single fish which contained botulinum spores after processing. (531-532). The absence of botulism in this litigation, except as a word conjuring up a host of horrors, is highly significant.

We believe the government is tilting at windmills.*

The preventions of the outgrowth of the botulinum spores by injuring them through a combination of heat treatment and application of salt is the supposed <u>raison d'etre</u> of the regulation (614, 618). Smoked whitefish is known to be and is marketed as a perishible product (332-336). As long as the fish is properly refrigerated there is not the

^{*} Defendant Nova Scotia has been in business some 56 years. There has never been a case of botulism illness from its whitefish (323-324).

least chance of outgrowth (572-574, 578). It is only when normal care is abandoned that a problem can conceivably arise. The GMP regulation is apparently intended, in its time-temperature-salinity requirement, to prevent outgrowth in the rare instance where the whitefish is abusively handled and where the bacteria happens to be present.

History has demonstrated, however, that the regulation is an unnecessary exercise because of the complete absence of even a single case of botulism related to whitefish since 1963.*

It is also clear that it is impossible for industry to comply with the regulation and produce a marketable product. At trial six witnesses, each engaged in processing, testified that they could not produce a marketable product if they had to comply with the GMP (278-281, 295-296, 300-302, 310-311, 351-356, 441-443).**

The learned trial judge indicated that the crossexamination of the processors demonstrated the existence of techniques which might permit processing at the GMP parameters

^{*} Indeed, the court below was unable to find a sufficient danger to health to justify the granting of a preliminary injunction (See Tscp. of Hearing, April 8, 1976).

^{**} As this testimony indicates: Whitefish brined to a level of 5% salt is far too salty for consumption and presents a clear health hazard to many persons (344-345); whitefish cooked to 180°F for thirty minutes becomes dry, flaky and inedible. The photographs received in evidence clearly show the devastating results of cooking at 180°F as compared with lower cooking temperatures (473-486; Def't. Exhs. "G" through "N").

and still yield a marketable product (771-773). We respectfully submit that this conclusion was erroneous. A careful
examination of the record demonstrates that in spite of extensive experimentation with the newest and most sophisticated
equipment industry members were unable, using any technique
imaginable, to produce a marketable product (350-354, 440-443).
The government did not offer one shred of evidence to demonstrate that methods did exist to achieve this result. The
government's questioning in this regard was entirely speculative and of the "When did you stop beating your wife" variety.*

Obviously, if some processing method existed which would admit of compliance and the production of a marketable product defendants and the industry would be only too happy to comply.

Further, the "taste-test" conducted at the trial clearly demonstrated the commercial unacceptability of white-fish prepared in accordance with the GMP (405-438). The government offered no evidence to the contrary.

The government's case was based solely upon a violation of the cited regulation. Its only witness testified as to facts which would show that whitefish processed by

^{*} For example the government asked if industry had sought help from an expert on thermal transfer (461-462, 464-465). However, the government did not demonstrate how such an expert could have helped; or that there is one available. In fact, there is no such expert (472).

defendants was not processed in accordance with the regulation. No attempt was made to demonstrate violation of the underlying statutory provision on which the regulation is allegedly bottomed. Indeed, the government conceded that there was no problem whatsoever as to sanitary conditions at defendants' plant (136, 348). Nor did the government offer any proof even remotely suggesting that defendants' whitefish may have become contaminated with filth or rendered injurious to health.

We shall discuss additional appropriate facts under the various point headings.

POINT I

THE REGULATION IS INVALID BECAUSE IT IS IN EXCESS OF THE STATUTE

The regulation under consideration here was proposed and promulgated solely pursuant to Sections 701(a) and 402(a)(4) of the Food, Drug & Cosmetic Act. (615, 618).

701(a), 21 U.S.C. 371(a), is strictly a grant of rule making authority. Section 402(a)(4), 21 U.S.C. §342(a)(4), is the sole substantive provision on which the regulation is based. That section, which sets forth one of the situations in which a food will be deemed adulterated, reads:

"A food shall be deemed to be adulterated -

(a)...(4) if it has been prepared, packed, or held under insanitary conditions whereby it

may have become contaminated with filth, or whereby it may have been rendered injurious to health."

As the proposal and adoption of the regulation as set forth in the Federal Register demonstrate (613-619) it is aimed at the prevention of botulism illness from the consumption of hot smoked fish. While that aim is to be lauded, the fact is that botulism is not a sanitation problem.

As noted above, clostridium botulinum is a natural organism. It exists in the water and mud of lakes and rivers. The whitefish come in contact with this natural organism merely by swimming in the water and eating food. If a fish is contaminated, it acquired the organism in its natural habitat.

The botilinum bacteria is not introduced into the fish as a result of dirt or other insanity conditions at the processing plant.* Thus, surgical standards of sanitation would not affect the presence or absence of this organism.

Its existence is wholly unrelated to sanitation as that term is used in the statute.

A. The Language Of The Statute Does Not Cover The In Plant Destruction Of Bacteria Naturally Present On The Fish At The Time Of Their Receipt In A Processing Plant.

The statute which ostensibly justifies the regulation provides that food is adulterated if it is "prepared,

^{*} The government conceded that it was "trying to control... something which is in the fish before it is caught and delivered to commerce." (159).

packed or held under insanitary conditions." Any regulation promulgated pursuant to the statute must therefore relate to these statutory elements if the regulation is to be valid. Obviously, regulations relating to plant sanitation are valid and proper. The present GMPs include a number of such items, though they are not in issue here.* What we do question here is the nexus between in-plant sanitation and the GMP's heating and brining requirements which are designed exclusively to inhibit the outgrowth of a naturally present bacteria which is not introduced as a result of inadequate sanitation at the plant where the fish are prepared, packed or held.

There is no definition of sanitation or "insanitary conditions" found anywhere in the statute; nor do the regulations attempt to define that term. It has, however, been held that the term should have its usual and ordinary meaning.

Berger v. United States, 200 F.2d 818 (8th Cir. 1952); United States v. 44 Cases, 101 F.Supp. 658 (E.D. III. 1951); United States v. Lazere, 56 F.Supp. 730 (N.D. Iowa 1944). This, of course, is a fundamental principle of statutory interpretation. Statutory language should be read in its "ordinary, everyday sense", Malat v. Riddell, 383 U.S. 569 (1966). Accord, Burns v. Alcala, 420 U.S. 575, 580-81 (1975); Banks v. Chicago Grain Trimmers Ass'n Inc., 390 U.S. 459, 465 (1968).**

^{*} See e.g., 21 C.F.R. §§128a.3; 128a.4(a); 128a.5; 128a.6.

^{**} The government agrees with this reading of the statute.

Memorandum Of Points And Authorities In Support of Preliminary Injunction, pp. 23-24

By any rational standard or definition, the term
"insanitary conditions" relating to the preparing, packing or
holding of food does not embrace the situation sought to be
dealt with by the regulation at bar. What the government
seeks is sterilization of the product in order to kill
naturally present bacterial elements. But sterilization
and sanitation are two very different things. Regulations
seeking sterilization cannot be adopted under the guise of
sanitation.*

The legislative history of the statute, as well as its consistent judicial application, make clear what common sense dictates: that "insanitary conditions" refers to the introduction of dirt, filth, roaches in a plant, dirty equipment and the like.

During the several years that the statute was being considered by Congress, the bill's sponsors consistently interpreted §342(a)(4) as dealing with cleanliness in the preparation of food products. When the bill was presented to the Senate following approval by the Senate Committee on Commerce, the Committee's report explained that this section was necessary to enable states to "protect themselves against interstate traffic in food from filthy plants in other states." S. Rep. No. 493,

^{*} If bacterial presence is in fact a health problem, the government has adequate remedy under other statutory provisions if the circumstances warrant. 21 U.S.C. §344(a) provides a method for dealing with food contaminated with microorganisms. But there is no basis for allowing FDA to proceed under a wholly inapplicable statutory provision.

73d Cong., 2d Sess. 5 (1934); S. Rep. No. 361, 74th Cong., 1st Sess. 7 (1935). See Hearings on S. 2800 Before the Senate Committee on Commerce, 73d Cong. 2d Sess. (Mar. 3, 1934).

Later, when the bill was first debated by the Senate, the primary sponsor of the bill explained the purpose of the section that became 21 U.S.C. §342(a)(4):

"While the present law prohibits traffic in foods which are filthy, it is unfortunately true that some extremely filthy products which find their way to market cannot be controlled for the simple reason that technical methods for the detection of filth in food products are woefully inadequate. To stop this menance, S. 2800 requires that foods shipped in interstate commerce shall be prepared, packed and held under conditions of reasonable cleanliness." 78 Cong. Rec. 8959 (73d Cong. 2d Sess. 1934) (Remarks of Senator Copeland)." (Emphasis added)

A similar interpretation of the section was offered by the bill's sponsor in the House of Representatives:

"There is a requirement in the bill that reasonable cleanliness be observed in the manufacture and handling of foods, drugs, and cosmetics. The present law contains no effective provisions along these lines, and many serious abuses in the sale of insanitary and unclean products are constantly occurring, with consequent sickness and death in various sections of our country. 80 Cong. Rec. 10236 (74th Cong. 2d Sess., 1936) (Remarks of Representative Chapman)." (Emphasis added)

In the court below the government asserted (Memorandum in Support of Injunction, pp. 23-25) that the legis-

lative history of the statute supports its contention that the statute was intended to permit the regulation of methods of processing food. However, even the portion of the legislative history relied upon by the government, when read in full context, indicates that the statute was intended only to deal with conditions of cleanliness:

"Mr. Campbell. I am referring to subsection 4, Senator. It is a requirement that exists in this form or in more exacting form in a great many of the State Laws. The only thing that it undertakes to do is to require the observance of a reasonable decent standard of cleanliness in the handling of food products. We have no control at all over that condition now. These States that have laws requiring all vendors of food to take precautions compatible with reasonable standards of sanitation cannot protect themselves against food products that are brought into their States from other States unless the exposure was so extensive that the product itself became filthy. In that event we could proceed; under the terms of the Federal law as it is now we cannot act unless the filthy condition had developed to a point where it is definitely obvious, and the product filthy.

Senator Herbert. Let me cite a case where this might work a hardship. A poor farmer produces milk and not under the most modern conditions. In fact, the barn may not be clean, although the milk is clean. He can prove to your satisfaction that his milk is clean. Nevertheless, if it is produced under insanitary conditions, then it may not be shipped in interstate commerce under the law.

Mr. Campbell. That is right. Sanitary conditions do not mean, however, the maintenace of tile floors or expensive establishments of that sort. Senator Herbert. No. I want to be reasonable.

Mr. Campbell. What you want, Senator, is the observance of those precautions which consciousness of the obligation imposed upon producers of perishable food products should require in the preparation of food for consumption by human beings." (Hearings on S. 2800 Before the Senate Comm. on Commerce, 73d Cong., 2d Sess. 1934 at 535-536).

This colloquy, of which only the last few lines were quoted by the government in its Memorandum, clearly shows that \$342(a)(4) was intended by Congress to deal with conditions of cleanliness, rather than methods of processing foods.

Officials of the Food and Drug Administration themselves have interpreted §342(a) (4) to apply only to standards of cleanliness. In an extensive discussion of the sanitation provisions of the Act, the Assistant Commissioner for Food and Drugs listed the conditions that were examined by sanitary inspectors. These included cleaning of equipment, provision of adequate toilet facilities, prevention of access by rodents and insects, the sanitation of raw materials such as water and ice, disposal of waste, and the general cleanliness of the plant. Larrick, "Sanitation Provisions of the Food, Drug and Cosmetic Act," Food, Drug, Cosmetic Law Quarterly, Vol. 1, pp. 164-165. This administrative interpretation of the statute is consistent with the Congressional intent that the statute protect against conditions of uncleanliness in the preparation or storage of food.

The courts have consistently agreed with this approach. There has been no reported decision which has applied the "insanitary conditions" provision of the statute to cover processing methods or sterilization. All of the reported cases have dealt with insanitary conditions as that term is commonly understood: United States v. Park, 421 U.S. 658 (1975) [access by rodents to factory]; United States v. Cassaro, Inc., 443 F.2d 153 (1st Cir. 1971) [contamination by insects and dirt; employees without head coverings]; United States v. Hammond Milling Co., 413 F.2d 608 (5th Cir. 1969), cert. denied, 396 U.S. 1002 (1970) [presence of rodent excretal matter]; United States v. International Exterminator Corp., 294 F.2d 270 (5th Cir. 1961) [presence of poison near foods]; Berger v. United States, 200 F. 2d 818 (8th Cir. 1952) [access by pigeons, flies, insects; rusty equipment; particles of grass and sticks in food; moldy food]; Triangle Candy Co. v. United States, 144 F.2d 195 (9th Cir. 1944) [presence of rats and cockroaches; generally unclean conditions]; United States v. Vermouth, Inc., CCH Food, Drug, Cosmetic Law Rep. (hereinafter cited as CCH) §2211.68 (D.N.H. 1974) [presence of mice]; United States v. 1200 Cans, Pasteurized Whole Eggs, 339 F.Supp. 131 (N.D. Ga. 1972) [use of dirty and unwashed eggs; ineffective sanitation of machines, implements and employees; presence of rodents and flies]; United States v. 1148 Cases, CCH ¶50,077.50 (D.C. Mo. 1963) [flies]; United States v. Palazzola, CCH ¶50,077.39 (D. Mich. 1955), [insects]; United States v. 44 Cases, 101

F. Supp. 658 (E.D. Ill. 1951) [presence of flies, maggots and decomposed food]; United States v. Lazere, 55 F. Supp. 730

(N.D. Iowa 1944) [presence of rodents and insects]; United States v. McGraw Candy Co., CCH ¶50,077.31 (D. Ala. 1943)

[rat infestation].

The regulation Itself is entitled: "Current Good Manufacturing Practice (Sanitation)" (618). This is a clear recognition by FDA itself that the statutory peg for the regulation is "sanitation". Yet, the heating and brining requirements are not related in any way to sanitation. They are concerned with an entirely separate matter.

With all deference, the court below grossly misinterpreted the statute and misread the authorities. To reach its
conclusion that the statute permitted the GMP regulation the
court termed the provision "inelegant" (735) and then judicially
rewrote the statute doing violence to its plain meaning and
language.

We submit that the statute is not "inelegant"; it is clear and simple. Its meaning should not have been expanded by judicial construction and interpretation. This is especially true in light of the fact that we are here dealing with a comprehensive set of specific statutory provisions each deliberately and carefully enacted to cover a definite

situation and which has explicit - albeit different - provisions dealing with the same general subject matter.

In reaching his conclusion that the statute was sufficiently broad to permit promulgation of the GMP regulation, the Court below relied upon two wholly inapposite authorities (736).

United States v. Coca Cola Co., 241 U.S. 265 (1916)*

provides no basis for the court's determination. The case did

not involve a naturally present element in Coca Cola but rather

turned upon whether a constituent part of Coca Cola syrup

(caffeine), could be deemed to be an adulterant. The decision

merely recognizes that a "proprietary food", made up entirely

by the formulation and combination of ingredients, fell with

the prohibition of the statute as it existed in 1916.

The case provides absolutely no basis for sustaining processing regulations unrelated to sanitation on the basis of a statute directed entirely toward sanitation.

The trial court's reliance on <u>United States</u> v. <u>Sprague</u>, 208 Fed. 419 (E.D.N.Y. 1913) was similarly misplaced.

In <u>Sprague</u> the defendants were indicted for shipping adulterated oysters. The statute defined adulterated to include food which "consists in whole or in part of a filthy, decomposed, or putrid animal or vegetable substance...." The court, on a

Cited by the Court below as <u>United States</u> v. Forty Barrels (736)

preliminary demurrer, held that the actual presence of bacteria could render food "filthy".

This provision has been carried forward into the present statute as 21 U.S.C. 342(a)(3) which defines a food to be adulterated "if it consists in whole or in part of any filthy, putrid or decomposed substance...." But we are not here concerned with FDA's power to promulgate a GMP under this statute* - a power which we doubt. The government has not even asserted the power to promulgate a GMP under this provision.

In Merck & Company, Inc. v. Kidd, 242 F.2d 592 (6th Cir. 1957), the Court had occasion to discuss the Sprague case. The Court noted (p. 595 fn. 1) that under present law the situation presented by Sprague might be covered by the statutory provision defining as adulterated food which "bears or contains any poisonous or deleterious substance which may render it injurious to health". This provision is now found in 21 U.S.C. 342(a)(1) -another separate statutory provision upon which the government does not rely in this case.

Sprague provides no basis for FDA's unwarranted excursion into legislation. The government based its case solely upon violation of the regulation, which is specifically bottomed on 21 U.S.C. 342(a)(4) and on no other statute. It cannot prevail by post-trial reliance upon statutory provisions whose

^{*} It must be remembered that the only substantive authority for the regulation is 21 U.S.C. 342(a)(4). The proposal and the regulation are explicit on this. (613-619).

violations were not even suggested in the complaint and which are not even proffered as being the basis of the disputed regulation.

These two decisions, each over sixty years old, simply do not justify the judicial rewriting of the statute.

The court below totally distorted the statute to broaden its coverage far beyond the language employed by Congress. As was noted in 62 Cases of Jam v. United States, 340 U.S. 593, 600 (1951):

"We see no justification so to distort the ordinary meaning of the statute."

In that case, the Court further noted (at 596):

"After all, Congress expresses its purpose by words. It is for us to ascertain - neither to add nor to subtract, neither to delete nor to distort."

In <u>Christover</u> v. <u>Poudre Valley Coop Assn.</u>, 235 F.2d 946 (10th Cir. 1956) the Court noted (at 950):

"Courts should confine themselves to the construction of a statute as it is written and not attempt to supply omissions or otherwise amend or change the law under the guise of construction."

And in <u>Story</u> v. <u>Snyder</u>, 184 F.2d 454 (D.C. Cir. 1950), the Court stated (at 459):

"It is not within the judicial function to rewrite a statute so that it will authorize what the court thinks should be authorized."

With all deference to the court below, it failed to adhere to these most fundamental canons of statutory construction when it rewrote the statute so as to authorize promulgation of the GMP regulation.

We respectfully submit that the regulation far exceeds its statutory base.

B. Since The Regulation Is Beyond The Statute It Is Invalid.

No principle of administrative law is more firmly rooted than the basic tenet that regulation must be within the parameters of the governing statute. As noted in <u>Manhattan</u>
Gen. Equip. Co. v. CIR, 297 U.S. 129 (1936) (at 134):

"The power of an administrative officer or board to administer a federal statute and to prescribe rules and regulations to that end is not the power to make law - for no such power can be delegated by Congress - but the power to adopt regulations to carry into effect the will of Congress as expressed by the statute. A regulation which does not do this, but operates to create a rule out of harmony with the statute, is a mere nullity."

The law in this regard was recently summarized in Real v. Simon, 510 F.2d 557 (5th Cir. 1975) (at 564):

"There can be no doubt that the authority of an administrative agency to promulgate regulations is limited by the statute authorizing the regulations. Thus, an administrative agency 'has no power to create a rule or regulation that is out of harmony with the statutory grant of its authority.' Ruiz v. Morten, 9 Cir., 1972, 462 F.2d 818, 822, aff'd 415 U.S. 199, 94 S.Ct. 1055, 39 L.Ed.2d 270 (1974). As the Suppose

Court has held, 'When Congress passes an Act empowering administrative agencies to carry on governmental activities, the power of those agencies is circumscribed by the authority granted.' Stark v. Wickard, 321 U.S. 288, 309-310, 64 S.Ct. 559, 571. 88 L.Ed. 733 (1944). 'Administrative determinations must have a basis in law and must be within the granted authority.' Social Security Board v. Nierotko, 327 U.S. 358, 66 S.Ct. 637, 643, 90 L.Ed. 718 (1946); see Morton v. Ruiz, 415 U.S. 199, 94 S.Ct. 1055, 1072-1973, 1075 (1974); Red Lion Broadcasting Co. v. FCC, 395 U.S. 367, 381, 89 S.Ct. 1794, 1801, 23 L.Ed.2d 371 (1969)."

Accord, East Texas Motor Freight Line, Inc. v. Frozen Food

Express, 351 U.S. 49 (1956); Bartels v. Birmingham, 332 U.S. 126

(1947); Social Security Board v. Nierotko, 327 U.S. 358 (1946);

Addison v. Holly Hill Co., 322 U.S. 607 (1944); Reardon v.

United States, 491 F.2d 822 (10th Cir. 1974); Celebrezze v.

Kilborn, 322 F.2d 166 (5th Cir. 1963).

In Reardon, the Court held (at 824):

"The Commissioner cannot promulgate regulations which impose a tax on the taxpayers which has not been imposed by legislative command."

Regulation which exceeds what Congress has authorized is void. Utah Power & Light Co. v. United States, 243 U.S. 389 (1917); Federal Maritime Comm'n v. Anglo-Canadian Shipping Co., Ltd., 335 F.2d 255 (9th Cir. 1964).

As stated by Justice Brandeis:

"The limits of the power to issue regulations are well settled. International Ry. Co. v. Davidson, 257 U.S. 506, 514. They may not extend a statute or modify its provisions." Campbell v. Galeno Chemical Co., 281. U.S. 599, 610 (1930).

The regulations here clearly modify and extend the statute and are patently invalid.

Nor is it the province of FDA to fix the limits of its power. That is a judicial function. As noted in <u>Social Security</u>

Board v. Nierotko, 327 U.S. 358 (1946) (at 369):

"An agency may not finally decide the limits of its statutory power. That is a judicial function."

In 62 Cases of Jam v. United States, 340 U.S. 593 (1951), in striking down FDA action as beyond the scope of its statutory authority, the Court noted (at 600):

"In our anxiety to effectuate the congressional purpose of protecting the public, we must take care not to extend the scope of the statute beyond the point where Congress indicated it would stop."

See also, <u>Toilet Goods Ass'n v. Finch</u>, 419 F.2d 21 (2d Cir. 1969) which struck down color additive regulations as beyond the scope of the statute.*

* * *

The GMP regulation which FDA seeks to enforce is designed to and admittedly was promulgated to prevent the outgrowth of botulinum spores which naturally occur on fish. The

^{*} It should be noted that the challenge to the regulation as being beyond the scope of the statute rests not only upon the general principles set forth above but upon the Administrative Procedure Act as well. The Act specifically recognizes that a Court may set aside agency action which is "in excess of statutory jurisdiction, authority or limitations, or short of statutory right." 5 U.S.C. §706(2)(C).

problem is totally unrelated to sanitation in any rational or traditional meaning of the term. But the prevention of "insanitary conditions" is the exclusive statutory peg for the regulation. Since the regulation is wholly unrelated to and unsupported by the statute, it is invalid.

POINT II

THE REGULATION IS INVALID BECAUSE FDA IMPROPERLY RELIED UPON UNDISCLOSED EVIDENCE IN PROMULGATING THE REGULATION. MOVEOVER, THE REGULATION IS NOT SUPPORTED BY THE ADMINISTRATIVE RECORD.

The conduct of FDA in proposing and adopting the regulation at bar violated the most fundamental concept of fairness and due process. At the trial it was disclosed, for the first time, that FDA relied upon a huge mass of scientific data in promulgating the regulation. Its reliance upon this data was not disclosed at any phase in the regulatory proceedings.

It was only during the preparation of this case for trial that disclosure was made as to the existence of, and FDA's alleged reliance upon, extensive scientific data. As part of their trial preparation defendants requested production of the administrative record (24-25). In response, FDA provides a mass of documents, mostly scientific in nature, which it claimed constituted the record. (The "purported record" was received in evidence as Defendants' Exhibit "D".).

The record was divided into a number of "Tabs" designated as "A" through "L". The Tab "A" material consisted of the publicly available documents as filed with the Hearing Clerk during the time the regulation was being considered (631-690). The documents in this Tab consisted of the proposed regulation, a few letters of comment and the regulation as adopted - nothing more.*

Tabs "B" through "L", which were unavailable to those persons interested in the matter and who were to be subject to the regulation, contained a mass of scientific and other material.

The record is clear that defendants and the industry had no notice that FDA, in its consideration of the regulation, had before it this mass of material (237-238, 255).

Moreover the "record" was assembled in a most unique way.

Apparently, FDA had no central file in which all of the materials used in its decisional process were assembled.

Nor did it even have a complete list. Instead, a young attorney who had been with FDA only a few months (265) was given the task of assembling the record (265, 34-36). Without intending to

^{*} Tab "A" - and only Tab "A" - had annexed an affidavit signed by the Hearing Clerk which affirmed that the Tab "A" documents constituted "the file" and were "part of the official records of the United States Food and Drug Administration" (631-632). No other portion of the "record" was so certified.

criticize the attorney in any way, he followed a unique procedure. He asked selected agency personnel to duplicate the materials which various people in the agency supposedly considered at the time the regulation was adopted (265-271). There is no suggestion that these individuals participated in the deliberative process and Mr. Friede was unable to state whether two of these three individuals were even employed by the agency at the time (266).

Nor did Mr. Friede have personal knowledge as to whether specific documents were in fact considered (273-274). He did not review the documents with those who produced them to ascertain this critical fact (274). Some of the documents had to be obtained from third parties because they could not even be found within FDA (268-269).

The industry was not aware of FDA's reliance upon these documents (237-238, 255).

It is thus clear that FDA acted without advising the parties subject to regulation of the factual basis for its action - whatever it was. When called to account, FDA created a huge post hoc mass of documents to support its action.*

^{*} FDA has suggested that appellants may not complain of this serious breach of their rights because there was no request made of FDA for disclosure at the time. However, the record is clear, and it is undisputed by FDA, that any such request would have been denied (258, 263-264) because at the time "FDA operated in a closet" (264). Further, industry representatives were unable to obtain data from persons outside the agency who had prepared material contained in Tabs "B" through "L" (248, 253-255).

A. The Basic Impropriety

It is axiomatic that agency action, including promulgation of a regulation, which is arbitrary, capricious, or an abuse of discretion, or which has not followed procedure required by law, can have no effect and is void. 5 U.S.C. §706(2)(A) and (D). And courts have repeatedly held that under this standard, a regulation must be supported in the administrative record by an adequate factual basis and by an adequate explanation of that basis in the regulation's accompanying "basis and purpose" statement. See e.g., Amoco Oil Co. v. EPA, 501 F.2d 722 (D.C. Cir. 1974).

Judicial review of agency action is impossible if there is not an adequate record upon which to predicate review. We submit that the record may not include secret data the existence of which was never disclosed to those about to be regulated.

Review should proceed on the basis of a public record made upon evidence fully disclosed to those involved. In the case at bar there was no such record.

As noted in Camp v. Pitts, 411 U.S. 138 (1973) (at 142):

"... the focal point for judicial review should be the administrative record already in existence, not some new record made initially in the reviewing court."

And in <u>Buckeye Power Inc.</u> v. <u>EPA</u>, 481 F.2d 162 (6th Cir. 1973), in vacating administrative action, the Court stated

(at 171):

"The Administrator built no record in approving or disapproving the state plans. He took no comments, data, or other evidence from interested parties, nor did he articulate the basis for his actions." (Emphasis Added)

In <u>Williams</u> v. <u>Robinson</u>, 432 F.2d 637 (D.C. Cir. 1970), the Court held (at 642):

"Similarly, since a primary function of judicial review of administrative action is to insure the integrity of the decision-making process and not merely to examine the correctness of the particular decision at issue, the agency may not support its decision by reference to facts outside the administrative record.... (Emphasis added)

It is, therefore, abundantly clear that agency action cannot proceed in a vacuum. An agency must create an administrative record which adequately supports its action. In the case at bar, there is no such record. An administrative finding made without supportive evidence is improper and beyond the power of the agency. United States v. Abilene & So. Ry., 265 U.S. 274 (1924).

The Constitutional right of due process mandates that a party to an administrative proceeding be advised of the underlying facts upon which the agency will act. As stated by the Supreme Court in Bowman Transp., Inc. v. Arkansas - Best Freight System, Inc., 419 U.S. 281 (1974) (288, Fn. 4):

"A party is entitled, of course, to know the issues on which decision will turn and to be apprised of the factual material on which the agency relies for decision so that he may rebut it. Indeed, the Due Process Clause forbids an agency to use evidence in a way that forecloses an opportunity to offer a contrary presentation."

In <u>Ohio Bell Tel. Co. v. PUC</u>, 301 U.S. 292 (1937) an order requiring a telephone company to make certain refunds was before the Court. In support of its action the Ohio Public Utilities Commission argued that it had taken judicial notice of price trends which it had withheld from the record and refused to reveal. The Court found this procedure to be a denial of due process, noting (at 300):

First: The fundamentals of a trial were denied to the appellant when rates previously collected were ordered to be refunded upon the strength of evidential facts not spread upon the record.

The Commission had given notice that the value of the property would be fixed as of a date certain. Evidence directed to the value at that time had been laid before the triers of the facts in thousands of printed pages. To make the picture more complete, evidence had been given as to the value at cost of additions and retirements. Without warning or even the hint of warning that the case would be considered or determined upon any other basis than the evidence submitted, the Commission cut down the values for the years after the date certain upon the strength of information secretly collected and never yet disclosed. The company protested. It asked disclosure of the documents indicative of price trends, and an opportunity to examine them, to analyze them, to explain and to rebut them. The response was a curt refusal. Upon the strength of these unknown documents refunds have been ordered for sums mounting into millions, the Commission reporting its

conclusion, but not the underlying proofs. The putative debtor does not know the proofs today. This is not the fair hearing essential to due process. It is condemnation without trial.

An attempt was made by the Commission and again by the state court to uphold this decision without evidence as an instance of judicial notice.

In rejecting the claim that the PUC action could be justified by the concept of judicial notice the Court stated (at 302-303):

What was done by the Commission is subject, however, to an objection even deeper. Cf. Brown v. New Jersey, 175 U.S. 172, 174, 175; West v. Louisiana, 194 U.S. 258, 262, 263. There has been more than an expansion of the concept of notoriety beyond reasonable limits. From the standpoint of due process - the protection of the individual against arbitrary action - a deeper vice is this, that even now we do not know the particular or evidential facts of which the Commission took judicial notice and on which it rested its conclusion. Not only are the facts unknown; there is no way to find them out. When price lists or trade journals or even government reports are put in evidence upon a trial, the party against whom they are offered may see the evidence or hear it and parry its effect. Even if they are copied in the findings without preliminary proof, there is at least an opportunity in connection with a judicial review of the decision to challenge the deductions made from them. The opportunity is excluded here. The Commission, withholding from the record the evidential facts that it has gathered here and there, contents itself with saying that in gathering them it went to journals and tax lists, as if a judge were to tell us, "I looked at the statistics in the Library of Congress, and they teach me thus and so." This will

never do if hearings and appeals are to be more than empty forms.*

the data upon which it will rely clearly includes test data and scientific literature. Appalachian Power Co. v. EPA, 477 F.2d 495 (4th Cir. 1973). The agency may not rely on data known only to itself, but must point specifically to the particular findings in the scientific literature relied upon, and to any pertinent data. Agency action is improper if such data has not been presented in a manner providing opportunity for comment, and in a manner providing an explanation of the agency position on any challenge. Portland Cement Association v. Ruckelshaus, 486 F.2d 375 (D.C. Cir. 1973), cert. denied, 417 U.S. 921 (1974). See also Hess & Clark, Division of Rhodia, Inc. v. FDA, 495 F.2d 975 (D.C. Cir. 1974).

Data known only to the agency cannot serve as a rule's foundation; nor can post hoc explanations of agency action. Ohic Bell Tel. Co. v. PUC, 301 U.S. 292 (1937).

Rodway v. United States Dep't of Agriculture, 514 F.2d 809 (D.C. Cir. 1975); Portland Cement Association v. Ruckelshaus, 486 F. 2d 375 (D.C. Cir. 1973), cert. denied, 417 U.S. 921 (1974); NLRB v. Groendyke Transport, Inc., 372 F.2d 137

^{*} In its opinion the court below indicated that portions of the secretly considered material "was either known to or readily accessible to any expert in the field to whom members of the class to be affected by the regulation would naturally have turned for advice and assistance." (770). However, as Ohio Bell makes clear, this is far short of the mark for it gave no opportunity to industry to know and meet the specific material involved.

(10th Cr. 1967), cert. denied, 387 U.S. 932 (1967); Burlington Truck Lines, Inc. v. United States, 371 U.S. 156 (1962). The agency's decision may not be supported by reference to facts outside the administrative record, nor by courses of reasoning disclosed for the first time in judicial proceedings. Williams v. Robinson, 432, F.2d 637 (D.C. Cir. 1970).

The Court must look at what the agency actually did, not what it might have done; an action cannot be upheld merely because findings might have been made and considerations might have been disclosed which would justify its order. SEC v. Chenery Corp., 318 U.S. 80 (1943); Rodway v. United States

Dep't of Agriculture, 514 F.2d 809 (D.C. Cir.1975).

In the case at bar, the industry had no information as to FDA's reliance upon the materials embraced in Tabs "B" through "L". Accordingly, it did not have a chance to comment upon them or offer additional materials in rebuttal. As a result, the regulation is invalid.

The court below suggested that appellants were not injured by the secret data considered by FDA because there was no evidence at trial to indicate that had the data been disclosed rebuttal data could have been presented which might have led FDA to a different conclusion (758-770)*. We submit that this conclusion is erroneous in two respects:

^{*} Indeed, the court below was unable to discern which of the material was actually relied upon by FDA (768-769).

- a) The question of whether industry, with full knowledge of the data, might have been able to present contrary evidence is irrelevant. The Court is faced here with a crass case of improper procedure by an administrative agency. In such a situation the Court should not speculate as to what might or might not have occurred if due consideration had been given to the rights of those being regulated.
- b) The court below overlooked and excluded testimony aimed directly at showing that the scientific evidence relied upon by FDA was inaccurate and not based upon a realistic appraisal of the true facts. Appellants attempted to introduce scientific evidence to demonstrate that in fixing the processing parameters FDA relied upon tests in which ground fish were injected with many millions of botulism spores and then tested for outgrowth at various processing levels whereas the spore levels in nature are far less and outgrowth would have been prevented by far less stringent processing parameters. There is a direct relationship between the number of spores and the rate of outgrowth. It takes lower levels of salt and heat to inhibit outgrowth of the bacteria in spore concentrations usually found in nature than the higher applications which are required when dealing with the multimillion spore loads artificially utilized by FDA. Evidence as to this critical area was excluded at trial. In short, appellants did demonstrate that the regulation was an unwarranted exercise in overkill

designed to prevent outgrowth in laboratory situations which were inconceivable in the real world. (545-586). Had industry known of the spore load upon which FDA was basing its determination it certainly would have been in a position to present evidence that far fewer spores existed in nature and that far less salt and heat were required.

The court below found that the materials included in Tabs "B" through "L" consisted of "neutral investigative studies" and that "it is not material of a kind that could lend itself to contradiction." (759). We submit that this conclusion is erroneous. As indicated above, the scientific studies were based on subjective assumptions which we believe were erroneous. Disclosure of FDA's reliance upon this data would have afforded industry an opportunity to rebut the erroneous underlying premises of these "neutral investigative studies".

It is clear that FDA prejudged the situation, promulgated an unwise regulation and now seeks to sustain it by reference to undisclosed inaccurate data which industry had no opportunity to meet and challenge. This impropriety goes to the very foundation of the regulation and requires that it be held invalid.

Further, not only must information relied on by the agency be disclosed, but it is a basic principle of administrative law that where there has been a determination of

disputed issues of fact, the agency must be able to point to procedures giving affected individuals a fair opportunity to challenge whether the determination is correct. <u>Williams</u> v. <u>Robinson</u>, 432 F.2d 637 (D.C. Cir. 1970). No such procedures were followed in this case.

It is significant to note that FDA has publicly adopted the view which we suggest here.

As has been stated by FDA's own Associate Chief Counsel for Food:

"... successful defense of a regulation on judicial review ultimately depends upon showing the court that the agency has conscientiously evaluated all views and data offered by interested persons and that its final regulation is supported by data and sound reasoning... judicial review may properly be restricted to the record compiled by FDA in the rule-making proceeding, i.e., a court in reviewing such a Section 701(a) regulation may properly refuse to receive additional evidence, and restrict its inquiry to determining whether the regulation is valid in light of the FDA's proposal, the documents filed with the Hearing Clerk, and the explantion offered in the final order (citations omitted, emphasis supplied).'
Remarks of Stephen Hull McNamara, Esq., Symposium on Food Regulations, University of Wisconsin, May 6, 1976.

And, a recent address by Mr. Richard Merrill, General Counsel to FDA, was reported by Food Chemical News of May 10, 1976, as follows:

"Stressing the need for placing all pertinent information in the record. Merrill noted that the courts 'will feel much more comfortable if an agency has in effect put all its cards on the table' and given opponents an opportunity to contest all premises..."

Mr. Merrill is also reported as stating:

"FDA's procedural regulations provide that the administrative record consists of such things as the petition or proposal, comments filed, preamble to the regulation and final order and the information on which the Commissioner relied in reaching his conclusion, Merrill noted.

He stressed that it is important for the record to contain source material supporting the agency's opinion rather than a simple statement that the agency 'knows' something to be so..."

Obviously, the procedure followed by FDA in promulgating the regulation at bar does not comport with that suggested by its own attorneys.

The position of Messrs. Merrill and McNamara is fully consistent with the requirements of the case law. The fact is that these requirements were ignored in promulgating the regulation at issue here.

Significantly, FDA has issued proposed* regulations which reflect, and are intended to bring FDA into compliance

^{*} Although the regulations are currently issued only as a proposal, it is clear that the agency fully intends that they be complied with. See remarks of Stephen Hull McNamara, supra. Indeed, FDA had promulgated these regulations in final form (40 F.R. 22984, 22992) but the District Court for the District of Columbia stayed the regulations as improperly promulgated. Subsequently the agency republished the regulations in the Federal Register as a proposal (40 F.R. 40681) which proposal is still pending.

with, the governing law as to what may be properly included in the administrative record. The proposed regulation states that the administrative record shall consist of:

"1) the petition initiating the regulation (if so initiated); 2) any petition for reconsideration or for a stay of action (and other documents resulting therefrom); 3) the notice of proposed rule-making in the Federal Register, including all data and information identified or filed by the Commissioner with the Hearing Clerk in support of the proposal; 4) all comments, including all data or information received as part of such comments; 5) the notice promulgating the final regulation, including all data and information identified or filed by the Commissioner with the Hearing Clerk in support of the final regulation and; 6) transcripts, minutes of meetings, reports, Federal Register Notices and other documents resulting from optional proceedings specified elsewhere." (emphasis supplied).

In contrast to the secretive procedure followed here, we would note that the notice of proposed rule-making for the bakery goods GMP regulations (41 F.R. 6456) issued under the same authority as the disputed provisions here, cites a number of plant inspections and reports and studies relied on, as well as reports of some four meetings held with industry representatives.* That notice, also in contrast to the proposal here, specifically states the agency's intention that the provisions are to have the binding effect of law.

^{*} This inclusion is particularly interesting in view of FDA's scrupulous avoidance of mention of the meeting held with the industry on the Smoked-Fish GMPs. That meeting, of course, resulted in unfulfilled promises by the agency to further consult with the industry and to publish a revised proposal. (225-227, 412-414).

Similarly, the Federal Register notice of proposed rule-making concerning restrictions in the uses of vinyl chloride polymers in contact with certain food and label statements (40 F.R. 40529) follows much more closely the required legal procedure. The notice cites several specific scientific studies which serve as a basis for the proposed regulation and states that the data on which the Commissioner relies is on file with the Hearing Clerk. Similarly, in National Nutritional Foods v. Weinberger, 512 F.2d 688 (2d Cir.) cert. denied, 423 U.S. 827 (1975), this court specifically noted (at 700) that FDA, contrary to its actions in this case, had revealed the scientific data upon which its action was based and afforded those concerned with an opportunity to "examine and criticize" that data.

Clearly, undisclosed material cannot form part of the administrative record and cannot be included therein. In the present case, the only disclosed material is the documents presented at Tab "A" of the purported administrative record (631-690). In none of these documents, which consist only of the two Federal Register Notices and a number of adverse comments, can any references to test data or scientific literature be found. The massive group of tests, articles and other references which the government has compiled at Tabs "B" through "L" were never filed with the Hearing Clerk, and cannot now be made part of the administrative record. Indeed, the documents noted at Tabs "B" through "L" were never shown by FDA to the industry, much

less to the public at large, as material relied on by the agency (237-238, 255). The industry, therefore, had no opportunity whatsoever to comment on this data, as required by the authorities noted above.

Moreover, there is no evidence that the material set out at Tabs "B" to "L" was ever actually considered by the Commissioner, nor is there, since the material was never filed with the Clerk, any evidence that this information even accompanied the regulation through the agency's decision-making process. Rather, the proceedings at trial indicated that the material was compiled by an FDA attorney specifically in preparation for this case, by asking various agency staff members what information had been "considered by the various people in the agency" (270-271). And the attorney who compiled the list of references acknowledged that the index to the materials did not even exist in 1970, when the regulation was under consideration, and that he had to go outside the agency to procure a number of the documents listed (268-269). This is precisely the kind of post hoc process specifically precluded by the authorities discussed above. (See particularly, Camp v. Pitts, 411 U.S. 138 (1973); Portland Cement Ass'n v. Ruckelshaus, 486 F.2d 375 (D.C. Cir. 1973), cert. denied, 417 U.S. 921 (1974). The purported record simply was not a "record" at the time of the regulation's consideration. Certainly the lack of any indication that the material was filed with the Clerk or

actually considered by the Commission is fatal to its inclusion in the record at this late date.

Government counsel has made much in these proceedings of the industry's failure to ask FDA for the data it relied on in proposing the rule. But the government has been unable to present, and counsel for defendants have been unable, after thorough research, to find, even one case or other authority which would impose such a burden on one who challenges a regulation. Rather, as discussed above, the authorities are all to the contrary, requiring the promulgating agency to produce and disclose data in the record to support a regulation. Members of the public cannot be expected to operate in a vacuum, asking an agency to produce documents the existence of which have never been indicated. The industry in fact did not know that these references were being considered by the agency and moreover, thought in good faith that, based on agency practice at the time in similar situations, any inquiry would be futile. The industry's failure to seek discovery of these documents can in no sense elevate them to the administrative record; only publication in the proposal or timely filing with the Hearing Clerk could have done that.

As the Court noted in NLRB v. Wyman - Gordon Co., 394 U.S. 759 (1969) (at 764):

"The rule-making provisions of that Act [APA], which the Board would avoid, were

designed to assure fairness and mature consideration of rules of general application."

These basic tenets of fairness and mature consideration have certainly been violated by FDA in this matter.

In Mobil Oil Corp. v. FPC., 483 F.2d 1238 (D.C. Cir. 1973), the Court held invalid rules promulgated by the FPC by informal rule-making such as was indulged in by FDA here.

After determining that the standard of review was substantial evidence, the Court had occasion to comment upon the so-called record (at 1259-1260):

"The FPC admittedly made findings of fact here regarding transportation costs and points to evidence which it claims supports the accuracy of these facts. It is clear, however, that none of the interested parties knew that this evidence - which was taken from a number of different sources - was to be the basis for the Commission's action. Consequently, no one was able to introduce evidence in opposition, criticize the Commission's position, or point out flaws by questioning the validity of its sources. As the record stands, in reviewing the Commission's action we are unable to decide whether its factual determinations are supported by substantial evidence. Much of the evidence appears possibly suspect, we have no way of knowing from the record whether the figures are valid. There is no evidence in the record except that which the Commission has chosen to include to support its position."

In short, in the case at bar appellants' rights were violated because FDA failed to disclose its reliance upon the great volume of material found at Tabs "B" through "L". Appel-

lants had no opportunity to rebut this material. And this Court has no basis to measure FDA's action against the applicable statutory standard.

We respectfully submit that FDA's improper conduct requires that the regulations be held invalid.

B. Even If FDA's Failure to Disclose
Its Reliance Upon Secret Data Does
Not Invalidate the Regulation, It
Still Must Be Declared Invalid
Because It Is Not Supported By
The Record

Although an agency engaged in rule-making need not resort to the often voluminous findings of fact issued following full evidentiary hearings, it must nevertheless provide a statement of the reasons for its decision, and where the agency's finding is not sustainable on the record made, its rule must be vacated. National Nutritional Foods Assn. v. Weinberger, 512 F.2d 688, 701 (2d Cir.), cert. denied, 423 U.S. 827 (1975); Amoco Oil Co. v. EPA, 501 F.2d 722 (D.C. Cir. 1974); cases cited supra Point II A.

Perhaps the most eloquent expression of a reviewing court's duty to examine the record in cases where a regulation is challenged may be found in the concurring opinion of Judge Lumbard in National Nutritional Foods Assn. v. Weinberger, supra at 705:

"In cases such as this, where an agency engages in substantive rule-making under the authority of a general rule-making authorization, the courts should interpret the phrase 'arbitrary, capricious, [or] an abuse of discretion' so as to ensure that real judicial review of agency action is provided. A district judge should carefully examine the information that was before the agency to see if it gives adequate and substantive support to the agency's position. While a court should not substitute its views for those of the agency, it should not think that the 'arbitrary [or] capricious' stand-ard is so loose that it must approve anything that an agency does so long as the agency's actions are not completely irrational. Indeed, in the area of substantive rule-making a court should not hesitate to overturn an agency's action if it is not fairly supported by the evidence before the agency.

In the case at bar the regulation is not supported by the administrative record, whether it be considered on the material contained at Tab "A" or on all of the material improperly considered by FDA.

1. The Material at Tab "A" Does Not Support the Regulation.

If, as suggested above, FDA's improper conduct does not totally invalidate the regulation, then, at the very least, it requires that the secretly considered material be excluded from the administrative record. Thus, we submit, that the true record consists only of the material at Tab "A".

Given the fact that the true administrative record consists solely of the materials at Tab "A", it is immediately apparent that the regulation is entirely unsupported by anything

except its own verbiage. This, of course, will not suffice.

There is not one shred of scientific evidence to support the regulation. The record is barren of any indication that the purported botulism hazard is related to insanitary conditions, or of any showing of reasonable possibility of injury to health, or as to commercial feasibility. The record is a non-record.

The documents filed with the Hearing Clerk consisted largely of adverse comments filed by the industry which do not provide any greater support for the agency position than does the proposal. To the extent there was a record at all before the Commissioner at the time the regulation was promulgated, it is woefully inadequate to support the detailed and specific provisions actually adopted.

The cursory record in this case stands in striking contrast to that developed in support of other FDA regulations. In National Nutritional Foods, supra, relied on by the government in support of the proposition that these regulations are legally binding, the Court found that (at 700):

"Before adopting the regulations, the FDA scrupulously followed the procedure prescribed by §4 [5 U.S.C. 553]. Appellants and all others concerned were given ample notice of the proposed action and an opportunity to submit documents, data and arguments ... Appellants not only set forth their own views and data in detail but were permitted to examine the opposing comments and data submitted by others and

to examine and criticize the medical literature relied upon by the FDA. It is undisputed that the FDA gave consideration to this mass of information in deciding whether to promulgate its proposed regulations." (Emphasis supplied).

In sum, the properly constituted administrative record in this proceeding simply does not support the regulation upon which the government has based this action, and counsel's post hoc compilation of authorities supposedly considered by various FDA staff members is not part of that record. There is no record which can be characterized as supporting the regulation. The regulation is invalid and of no effect.

 Even The Lengthy Version Of The Administrative Record Proffered By FDA Does Not Support The Regulation.

Even the lengthy "record" (Def't. Exh. "D") compiled by FDA does not provide any basis for the GMP regulation. While the record contains a wealth of scientific materials, it is woefully deficient in three areas:

- (a) It fails in any way to relate the botulismproblem if there be one at all to insanitary conditions;
- (b) It fails to demonstrate that there is a reasonable possibility of injury to health;
- (c) It fails to demonstrate the commercial feasibility of the processing parameters contained in the regulation.

We have carefully examined the extensive collection comprising the so-called administrative record. Nowhere in it is there to be found data sufficient to supply any basis for finding a nexus between sanitation and botulism; nor is there any basis for finding any reasonable possibility of injury to health from botulism in hot smoked whitefish other than vacuum packed whitefish; nor is there any fair consideration given to processing parameters which are attainable by industry.

a. The Absence Of Any Relationship To Sanitation.

A reading of the "record" demonstrates that Clostridium botulinum is a natural organism which exists in the water and mud of lakes and streams. The bacteria come in contact with the fish as they swim and feed. There is extensive material throughout Tab "B" which clearly demonstrates this basic proposition. Tab "F-63" points out that botulinum spores which may be found in fish after processing are indigenous to the raw material.

One may search the "administrative record" from cover to cover but will not find a single reference to insanitary conditions in the preparing, packing or holding of whitefish as being the source of botulinum spores. There is no suggestion that spores contaminate the fish as a result of dirt, rodents, dirty hands or filth introduced during pro-

cessing. There is no suggestion that the cleanest possible conditions would alleviate any alleged botulism hazard.

Concededly, there is extensive data on how to kill (or inhibit the growth of) botulinum spores by use of heat, nitrites and salt in varying combinations. But these matters are unrelated to sanitation - they are concerned with sterilization, a wholly disparate subject which is not covered by the statute under which this regulation was promulgated.

Thus, it is clear that even the extensive "record" created by FDA for this trial does not suffice to support its regulation.

b. No Reasonable Possibility Of Injury To Health.

The 70 items collected at Tab "F" contains certain reports as to the occurrence of botulism illness in the United States. A study of the items (See particularly Tabs "F-4", "F-23", "F-30", "F-31" and "F-32") confirms a number of cases in 1960 and an additional number in 1963, all arising from vacuum packed whitefish. There is not one single reported case other than the 1960 and 1963 incidents.

In adopting the GMP, FDA totally ignored the fact that vacuum packaging had been abandoned. It also gave no consideration to the fact that there had not been a case of botulism from commercially processed hot smoked whitefish until 1960 or after 1963.

In sum, we suggest that any possibility of injury to health from commercially prepared hot-smoked whitefish is remote - not reasonable. Hence, the second statutory basis for the regulation is non-existent.

c. Lack Of Consideration Of Commercial Feasibility.

Finally, FDA ignored the fact that a commercially acceptable product could not be produced in compliance with the GMP. The letters of comment contained at Tab "A" - as well as those that were improperly omitted (622-630) - clearly make this point.

There is nothing in the "record" which refutes these comments and demonstrates the ability of industry to comply with the regulation and produce a marketable product.*

Tab "D-3" of the "record" contains a report prepared by FDA on cooking. Page 5 contains the following:

"A taste panel consisting of 39 people from the New York District FDA office compared the chubs made during this phase to those made by commercial methods. Although 79% of the panel preferred the commercially prepared whitefish according to taste and 87% voted in favor of the commercially prepared whitefish according to appearance, our product was not unsaleable."

This appears to be the only data as to marketability. It is woefully deficient and obviously leaps to a totally un-

^{*} The trial evidence graphically demonstrated that a commercially acceptable product could not be produced in accordance with the regulation.

justified conclusion. There was no attempt to market the whitefish produced by FDA and even though the panel was not an objective group it overwhelmingly rejected the product. The conclusion of saleability is pure speculation. Moreover, this is precisely the kind of material which industry could have easily refuted had it been aware of its existence and FDA's reliance thereon. Indeed, the evidence received at trial clearly demonstrates the erroneous character of this material.

Thus, here, too, FDA ignored the evidence and the facts in deciding to promulgate this regulation.

* * *

The court below concluded that the material in Tabs "B" through "L" "added nothing of moment to what is in the formal record" (768). If this conclusion is correct it necessarily follows that there is nothing in the record which even remotely supports the regulation.

We respectfully submit that even the extended record relied upon by FDA provides absolutely no support for the GMP regulation. As a result it is invalid.

POINT III

THE REGULATION IS INVALID BECAUSE OF THE ABSENCE OF AN ADEQUATE STATEMENT SETTING FORTH THE BASIS OF THE REGULATION.

This Court is not required to attempt to discern from an administrative record which factors and considerations

motivated the promulgation of a regulation. The agency must provide "a concise general statement of [the regulation's] basis and purpose" 5 U.S.C. §553(c). As this Court has stated a "thorough and comprehensible" statement is advisable and, at a minimum, the statement must be "sufficiently detailed" to permit judicial review. National Nutritional Foods Ass'n. v. Weinberger, supra, at 701. See also, Associated Ind. of N.Y., Inc. v. Department Of Labor, 487 F.2d 342 (2d Cir. 1973).

Nor, as noted above, may an agency seek to sustain its action by after the fact rationalization.

In <u>E. I. DuPont de Nemours & Co.</u> v. <u>Train</u>, 541 F.2d 1018 (4th Cir. 1976) the Court stated (at 1026):

"The grounds upon which the agency acted must be clearly disclosed in, and sustained by, the record. Federal Trade Commission v. Sperry and Hunchinson Co., 405 U.S. 233, 249, must "explicate fully its course of inquiry, its analysis and its reasoning." Ely v. Velde, 4 Cir., 541 F.2d 1130, 1139; see also Appalachian Power Company v. Environmental Protection Agency, 4 Cir., 477 F.2d 495, 507. After the fact rationalization by counsel in brief and argument does not dure non-compliance by the agency with the stated principles. Dry Color Manufacturers' Association, Inc. v. Department of Labor, 3 Cir., 486 F.2d 98, 104, and particularly cases cited in n. 8.

As noted in National Renderers Ass'n. v. EPA,
541 F.2d 1281 (8th Cir. 1976):

"Our task is to determine whether the EPA's decision is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with

law." 5 U.S.C. \$706(2)(A); Citizens to Preserve Overton Park v. Volpe, 401 U.S. 402, 416, 91 S.Ct. 814, 28 L.Ed.2d 136 (1971); CPC International Inc. v. Train, 515 F.2d 1032, 1044 (8th Cir. 1975) (CPC I). To enable us to perform that task, the EPA must explicate fully its course of inquiry, its analysis and its reasoning. Appalachian Power v. EPA, 477 F.2d 495, 507 (4th Cir. 1973); Kennecott Copper Corp. v. Environmental Protection Agency, 149 U.S. App. D.C. 231, 462 F.2d 846, 848-849 (1972)."

Within this legal framework, then, it has been consistently held that the basis and purpose statement must set forth a full articulation of the agency's course of inquiry, analysis and reasoning. The grounds upon which the agency acted must be clearly disclosed and adequately sustained.

Appalachian Power Co. v. EPA, 477 F.2d 495 (4th Cir. 1973);

SEC v. Chenery Corp., 318 U.S. 80 (1943).

In contrast to the required statement, the two sentences which constitute the substantive portion of the basis and purpose statement of the final regulations are cursory. They state (618):

"The principal objection is that the process requirements in the proposed regulations cannot be applied to all species of fish presently being smoked by the industry and that the regulations should therefore specify time-temperature requirements, as developed by research and study, on a species-by-species basis.

The Commissioner finds: (1) That although adequate times, temperatures, and salt concentrations have not been demonstrated for each individual species of fish presently smoked, the processing requirements of the proposed regulations are the safest now known to prevent the outgrowth and toxin formation of Botulinum Type E; and (2) that since

the public health hazard of Botulinum Type E in smoked fish is not restricted to a single species of fish, the conditions of current good manufacturing practice for this industry should be established without further delay."

Surely this terse statement is not "sufficiently detailed and informative to allow [the] searching judicial scrutiny" required by Amoco Oil Co. v. EPA, 501 F.2d 722, 739 (D.C. Cir. 1974) and the cases we have cited. Nor does it constitute the "sufficiently detailed" statement called for by National Nutritional Foods.

Significantly, the basis and purpose statement does not respond to crucial comments raised during the commenting period. For instance, the Association of Smoked Fish Processors stated that certain of the requirements were "neither commercially feasible nor based on sound scientific evidence," and that a desirable alternative might include lower temperature processing in combination with specific salt and nitrite levels (648-653). Similarly, the defendant Nova Scotia Food Products Corporation commented that the heating of certain types of fish to the required temperatures would destroy the product (654-656). Intervenor National Fisheries Institute submitted eight pages of comments, including a number of proposed amendments on all phases of the regulation, including comments on the desirability of the use of nitrites with lower temperatures as an alternative to the proposed requirements (664-672). These, and other submissions, are important comments which go to the heart of the

provisions at issue here. FDA's failure to respond falls far short of legal requirements and renders its statement totally insufficent to support the regulation.

"The substantive discussion of the basis for the GMP regulation makes no reference at all to the numerous secret reports or studies. Most significantly, no justification whatever is given for the specific provisions, including the temperature and salt content provisions, which are at issue in this case. The hazard botulism is assumed, not discussed. Nor is anything set forth which relates the alleged hazard to "insanitary conditions".

The basis and purpose statement is woefully deficient and, as a result, the regulation is invalid.

POINT IV

THE GOVERNMENT FAILED TO PROVE THE NECESSARY ELEMENTS OF ITS CASE.
MERE VIOLATION OF THE REGULATION IS NOT A SUFFICIENT BASIS FOR THE GRANTING OF THE INJUNCTION.

A. Given All Of The Circumstances The Regulation Should Be Treated As Merely Interpretive.

We recognize that in <u>National Nutritional Foods Assn.</u>
v. <u>Weinberger</u>, 512 F.2d 688 (2d Cir.), <u>cert denied</u>, 423 U.S. 827 (1975), this Court indicated that FDA regulations were entitled to the force and effect of law. However, in this specific instance we believe that such an application is unwarranted.

There are several factors which so indicate.

Foremost among these is the manner in which the regulation was proposed and adopted and FDA's utilization of secret data. If a regulation is to bind an industry, then the industry must have a reasonable opportunity to challenge it during its course through the agency.

It was not until October 1969 that the proposed regulation was published in the Federal Register (225, 613-616).

No advance warning was given and industry first learned of the regulation through its publication (225). The notice required comments within thirty (30) days.

As noted above, various comments were submitted.

Thereafter a meeting was held with Gen. Fred Delmore of the FDA (230-231). At the meeting, industry again voiced its strong objections to the proposed GMP and was led to believe that a new proposed GMP would be issued. Instead, without the least warning and without further discussion with industry, the regulation was made effective. (225-230, 236-237, 412-416, 617-619).

Industry was advised and believed that the regulations were guidelines and were not binding (348-351, 445).

Nor did FDA indicate its view that the regulations were to be more than mere guidelines.* Moreover, FDA had previously

^{*} See discussion of other proposed GMP regulations, supra, p. 37 where FDA gave clear notice that the regulations were to be binding.

indicated that this was its own view of the matter. In September 1967 FDA's Director of Regulatory Compliance published an article in Food, Drug, Cosmetic Law Journal (at p. 511) in which he specifically stated that actions under the insanitary conditions provisions of the adulteration statute "still have to be based on evidence sufficient to prove a violation of the section and sufficient evidence for their purpose will sustain conviction, regardless of the existence or content of CGMP regulations." Thus, industry clearly was entitled to believe that they were not faced with binding regulations having the full force and effect of law.

After adoption of the regulation, further and consistent advice was given to FDA that industry could not comply (345-352, 691-701; Pltf. Exh. 6 at Prelim. Discussion and 35-36; Pltf. Exh. 7 at 27-28). In the face of repeated non-compliance and inability to comply, FDA did nothing for six years thus lulling the defendants and industry into the belief that the regulations were non-binding guidelines (345-352).

Given this history of haughty administrative procedure, obvious misconceptions by defendants fostered by agency inaction and sudden enforcement, we submit that the regulation should be treated as interpretative and not as having the force and effect of law.

B. Mere Violation Of The Regulation Is Insufficient To Support The Granting of Relief.

This suit is founded upon section 302(a) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. \$332(a).

That section vests the Courts with jurisdiction "to restrain violations of section 301 of this title [21 U.S.C. §331...]".

Section 301 of the Act contains a list of prohibited acts. Paragraph 10 of the complaint (8) charges a specific violation of section 301(k), 21 U.S.C. §331(k). That provision states:

"The following acts and the causing thereof are prohibited:

(k) The alteration, mutilation, destruction, obliteration or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a food, drug, device or cosmetic, if such act is done while such article is held for sale (whether or not the first sale) after shipment in interstate commerce and results in such article being adulterated or misbranded."

It will be noted that the quoted provision prohibits the "doing" of affirmative acts which result in food "being adulterated." The term "adulterated" is not defined in that section, but a comprehensive definition is found in section 402(a) of the Act, 21 U.S.C. \$342(a). Paragraph 9 of the complaint (7-8) charges only a specific violation of Section 402(a)(4), 21 U.S.C. 342(a)(4). That section provides:

"A food shall be deemed to be adulterated -

(a)...(4) if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health;"

"Adulteration" under this provision depends upon a showing of "insanitary conditions" and upon proof that the product has "become contaminated" or been "rendered injurious" to health. There was absolutely no such proof in the case at bar.

The statutory power granted to the Court is to enjoin violations of section 301, 21 U.S.C. §331(k), which contains a catalogue of prohibited acts. Nowhere in that section is it stated that violation of a regulation promulgated by FDA is a "prohibited act." Yet violation of the regulation was the sole basis of the government's case.

There is simply no lisis in the statute for the granting of injunctive relief based upon the mere showing of a violation of a regulation - especially one promulgated and enforced in the manner of this GMP.

This is a civil action in which the government seeks injunctive relief. As a plaintiff, it has the obligation of any other litigant: to prove its case. In food, drug and cosmetic cases - like any others - the burden rests with the plaintiff. United States v. Lexington Mill & Elevator Co., 232 U.S. 399, 411 (1914); United States v. 1500 Cases, 236 F.2d 208, 213 (7th Cir. 1956); United States v. 47 Bottles, 320 F.2d 564, 570 (3d Cir. 1963); United States v. 4 Cases, 300 F.2d 144; 148 (7th Cir. 1962).

In order to sustain its claim, the government was required to prove all of the elements of its case. The fact that defendants may have violated a regulation does not, in and of itself, entitled the government to relief. There is no authority to support the view that violation of a regulation requires the granting of relief against the violator. The most recent case to have considered this matter is <u>United States</u> v. Everett Fisheries, 71-CR-109 (W.D. Wis. Dec. 31, 1975) which rejected any such notion. In <u>Everett</u>, Judge Doyle wrote:

"Early in the course of this case, I rejected the government's contention that if food has been prepared, packed or held in a manner which does not meet the requirements of 21 CFR §128a, it follows necessarily that it has been prepared, packed or held 'under insanitary conditions whereby... it may have been rendered injurious to health... .' This was a contention that Congress had made it a crime to violate any FDA regulation duly promulgated pursuant to the Act. But Congress clearly has not chosen this course. I concluded, and I continue in the view, that in each criminal prosecution under 21 U.S.C. §§331(a) and 333, the government must prove beyond a reasonable doubt, not that the FDA regulations have been violated, but that the food was adulterated within the meaning of 21 U.S.C. §342."

Accord, United States v. Lord-Mott, Co., Inc., 57 F. Supp. 128
(D. Md. 1944).

The same conclusion is suggested in an article entitled "Authoritative Effect of FDA Regulations" 1969 Food,
Drug, Cosmetic Law Journal 195 where Mr. William Cody states
(at 209):

"The requirement of a reasonable possibility of contamination, etc., has been held essential to the constitutionality of the Insanitary Conditions Provision of the Food Drug and Cosmetic Act in Berger v. U.S. Each claimant or defendant in an enforcement action should therefore have full opportunity to litigate this "reasonable possibility" in the light of the specific practice or condition involved in his case, as a basic "adjudicative fact" issue as to which he is entitled to an individual hearing by the Court. Fundamental considerations of fairness, and constitutional due process, would seem to require no less."

Indeed, the position taken by FDA in this litigation that mere violation of a regulation is sufficient to support
injunctive relief - is directly contrary to its own previously
announced views. In 1967, Mr. Alfred Bernard, FDA's Director
of Regulatory Compliance, addressed himself to this very
problem in an article published in the September issue of Food,
Drug, Cosmetic Law Journal (p. 511) entitled "Good Manufacturing
Practices Regulations in the Food Industry."

In discussing the GMP regulations and their relation to Section 402(a)(4), 21 U.S.C. 342(a)(4), the insanitary conditions provision, Mr. Bernard states (at 514):

"Action under Section 402(a)(4) will still have to be based on evidence sufficient to prove a violation of the section and sufficient evidence for this purpose will sustain conviction, regardless of the existence or content of CGMP regulations."

In this case there was absolutely no proof offered as to violation of the governing statute.

We respectfully submit that the judgment below must be reversed because the government totally failed to prove the required elements of its cause of action.

POINT V

THE INJUNCTION ISSUED BELOW IS HARSH AND OPPRESSIVE

We respectfully suggest that the court below was not required to grant the broad injunctive relief sought by the government merely because appellants were not in compliance with the regulation. Rather, the court should have considered a variety of equitable factors which bore heavily upon what relief, if any, should have been granted even though defendants may have violated the cited regulation. This it did not do.

to health from smoked whitefish is nil. The raison d'etre of the regulation is the prevention of botulism. Yet the undisputed evidence shows that since 1899 there have been only 8 outbreaks of botulism from commercially prepared hot-smoked whitefish. These occurred in 1960 and 1963 and were associated with vacuum packed products. Vacuum packaging created a specific problem because of delayed spoilage mechanisms. Vacuum packaging has been abandoned and there has been no problem since 1963. This absence of a single outbreak since 1963 must be read in light of the fact that 2,750,000 pounds of whitefish are smoked annually. Thus, from 1964 through 1976, 35,750,000

pounds of commercially smoked whitefish have been sold without a single reported case of botulism. In 56 years of business, Nova Scotia has never had a botulism problem. Nor has there ever been a commercial problem arising from whitefish prepared and distributed other than by vacuum packaging.

It is well settled that even in cases involving violations of statute, a court has an equitable function to perform and may grant, withhold or condition relief in its discretion and as the equities of the situation dictate.

The classic formulation of the rule is found in Hecht Co. v. Bowles, 321 U.S. 321 (1944). That case involved the propriety of injunctive relief against price control violations. In holding that violation did not in and of itself require the automatic granting of injunctive relief, Justice Douglas, speaking for the Court stated (at 329-330):

"We are dealing here with the requirements of equity practice with a background of several hundred years of history. Only the other day we stated that 'An appeal to the equity jurisdiction conferred on federal district courts is an appeal to the sound discretion which guides the determinations of courts of equity.' Meredith v. Winter Haven, 320 U.S. 228, 235. The historic injunctive process was designed to deter, not to punish. The essence of equity jurisdiction has been the power of the Chancellor to do equity and to mould each decree to the necessities of the particular case. Flexibility rather than rigidity has distinguished it. The qualities of mercy and practicality have made equity the instrument for nice adjustment and reconciliation between the public interest and private needs as well as between competing private claims.'

Accord, United States v. W. T. Grant Co., 345 U.S. 629 (1953);

Esquire, Inc. v. Esquire Slipper Mfg. Co., 243 F.2d 540 (1st

Cir. 1957). For an example of this equitable shaping of relief
in the misbranding area, see United States v. Article of Drug,

362 F.2d 923 (3rd Cir. 1966).

We submit that the court below failed to give adequate consideration to several factors.

A. The Injunction Sought By the Government Would Destroy The Whitefish Business

It is abundantly clear that a commercially marketable whitefish cannot be produced in compliance with the GMP. Fish cooked at 180° is burned, dry and unsaleable. Fish brined to achieve a 5.0% salt level is too salty for consumption - not to mention the health hazard associated with salt intake at the high levels required by FDA.

The undisputed testimony at trial by smokers and by retailers was that fish cooked in accordance with the GMP cannot be sold. Thus, injunctive relief here would cause the termination of the sale of whitefish - an \$8,000,000 industry (451).

We recognize that inability to comply might not create sympathy for appellants' plight if the non-complying product were truly dangerous. But this is not the case. The facts clearly demonstrate the absence of any reasonably conceivable chance of harm to the consuming public.

In considering the requested relief, we submit that the court below should have balanced the right to engage in business against the vastly remote chance of harm. It must be remembered that this is a protected right under the Fifth and Fourteenth Amendments to our Constitution. Allgeyer v.

Louisiana, 165 U.S. 578 (1897); Butchers' Union Co. v. Crescent City Co., 111. U.S. 746 (1884); Bolling v. Sharpe, 347 U.S. 497 (1954); Greene v. McElroy, 360 U.S. 474 (1959); Madera v.

Board of Education, 386 F.2d 778 (2d Cir. 1967); cert. denied, 390 U.S. 1028 (1968); Shaw v. Hospital Authority, 507 F.2d 625 (5th Cir. 1975); Milnot Co. v. Richardson, 350 F. Supp. 221 (S.D. III. 1972).

This right should not have been so lightly disregarded.

B. The Need For An Appropriate Delay In The Effective Date Of the Injunction.

During trial and by way of post trial presentation appellants clearly demonstrated that there was good reason for a delay in the effective date of the injunction.

One important reason is FDA's own inaction upon a petition filed in 1971 seeking permission to use sodium nitrite in the processing of whitefish thereby permitting a substantial lowering of the salt-temperature requirements.* Sodium nitrite

^{*} FDA has granted such approval with respect to chubs (754).

is an effective inhibitor of botulinum outgrowth. Approval of the use of nitrite would provide the level of protection FDA apparently seeks but still permit the production of a marketable product. FDA has failed to act on that petition. (490-498; Def't. Exh. O).

Appellants requested that the court below compel FDA to act on this petition but no such relief was granted. The court should have granted redress against the "pocket veto" of this petition.*

This situation is covered by the Administrative Procedure Act. 5 U.S.C. §702 gives any aggrieved party a right of review. And under section 706 a Court can "compel agency action unlawfully withheld or unreasonably delayed." This is precisely the situation here. The Secretary has failed to act on the Whitefish Petition for five (5) years to the great detriment of the industry. And, of course, defendants' failure to challenge his inaction prior to this time does not prejudice their rights. 5 U.S.C. §703 expressly provides:

"Except to the extent that prior, adequate and exclusive opportunity for judicial review is provided by law, agency action is subject to judicial review in civil or criminal proceedings for judicial enforcement."

Since there was not a "prior, adequate and exclusive" review mechanism available as to the <u>sub silento</u> denial of the Whitefish Petition, and since defendants are clearly aggrieved by that denial, we submit that this litigation is an appropriate arena for the determination of that issue.

^{*} The court below clearly had power to act. A careful reading of the applicable statutory provisions indicates the authority of this court. The Whitefish Petition was a food additive petition submitted under Section 409 of the Act, 21 U.S.C. §348. Subdivision "c" requires action by the Secretary within specified time limits. Once the Secretary acts subdivision "f" affords a right of hearing to an aggrieved party. An order rendered by the Secretary following a hearing is subject to exclusive jurisdiction of the United States Courts of Appeals "to affirm or set aside the order in whole or in part." (Sub. "g"). The statute is entirely silent as to an aggrieved party's rights when the Secretary simply fails to act.

Further, the record clearly indicates that important scientific research is underway which will allow industry to submit factual data to FDA that would demonstrate the excessive nature of the processing parameters imposed by the present GMP. Industry is also submitting additional data with respect to the nitrite application so as to demonstrate the propriety of its use. All of this requires time. The research is moving along rapidly and the results are favorable. (783-790, 800-803).

The court below should have afforded appellants a reasonable opportunity to complete their research, to present it to FDA and for FDA to act thereon before the injunction became effective.

As suggested below, a two year delay was necessary and appropriate and should have been granted.

C. The Selective Enforcement Of The Regulation Was Unfair To Defendants-Appellants

No competitor of Nova Scotia produces its fish in accordance with the GMP. If appellants are enjoined, they will quickly lose their whitefish trade to their competitors. The loss, however, will extend far beyond whitefish; patronage will be lost for other products because of appellants' inability to provide a full line of products and could result in defendants going out of business and throwing their employees out of work. (355-259). Indeed, this such has resulted in

the abandonment of a planned renovation and reconstruction of defendants' plant (340-342, 379-381).

Enjoining only the defendants from processing whitefish except in strict compliance with the GMP accomplishes
little, if anything, insofar as any alleged hazard to health
is concerned. Nova Scotia is only one processor out of many.
Its smoked whitefish production prior to the granting of the
injunction amounted to approximately 130,000 pounds per year
(324) or less than 5% of the total amount smoked per annum
(2,750,000 pounds). Certainly, if a health hazard actually
does exist, (which seems extremely remote) enjoining these
defendants will not materially reduce such hazard to health.

Moreover, it stands to reason that if these defendants are restrained, and all other processors are not, the vacuum caused by the cessation of production of smoked whitefish by the defendants will be filled by additional production by other processors. Thus, restraining defendants serves no useful purpose whatsoever. All it can accomplish is to substantially cut down defendants' business thereby causing them and their employees unnecessary hardship.

We submit that the harsh remedy of injunction should not have been imposed upon the defendants under these circumstances. The court should consider all the relevant facts and, in exercising its equitable powers, deny the injunction,

or in the alternative, stay it for the requested period of two years during which:

- (a) Defendants (and industry) will be afforded a reasonable opportunity to comply with the relevant GMP; or
- (b) Defendants (and industry) will be afforded a reasonable opportunity to seek, and hopefully procure, a modification of the GMP which will enable them to market an acceptable product; or
- (c) FDA will be afforded a reasonable opportunity to deal with substantially all processors of smoked whitefish in the same manner.

The spot enforcement being undertaken by FDA is inappropriate. FTC v. Universal-Rundle Corp., 387 U.S. 244 (1967);

Moog Industries, Inc. v. FTC, 355 U.S. 411 (1958); Marco Sales

Co. v. FTC, 453 F.2d 1 (2d Cir. 1971). We respectfully suggest
that appellants should not have been enjoined prior to the
imposition of similar restraints upon their competitors.

CONCLUSION

The warning sounded by the District Court in <u>United</u>

States v. <u>Lord-Mott Co., Inc.</u>, 57 F.Supp. 128 (D. Md. 1944), over thirty years ago bears repetition here:

"Finally, the Court desires to point out that its conclusion is based upon the view that the primary object of the provisions of the Act under which this case has been brought is to protect the consumer public from adulterated and misbranded foods. We are here only concerned with foods, although the Act deals with other things. Underlying that protection is, of course, the basic idea of the promotion and preservation of health, through production and distribution of food which is not deleterious, but healthy. This, of course, presupposes that the public shall be protected from deception as to the true character of the food that is being shipped in interstate commerce. Certainly, the Government is the proper agency to surround the public with the safeguards that are necessary in order to prevent such food from being adulterated and misbranded. But this Court believes that any regulation passed in furtherance of these basic principles exceeds the legitimate bounds of administrative regulation if it does not operate fairly and reasonably with respect to the producers or distributors of the articles involved, as well as with respect to the consumer public [emphasis added]. It is true the Administrator is vested with broad, discretionary authority. It is also true that, for this reason, his findings are to be accepted as conclusive if supported by substantial evidence, provided always, however, they are within statutory and constitutional limitations.... In the present case, we find they are not within either limitation. 57 F.Supp. at 133.

The regulation at bar is far beyond the power of FDA and it was promulgated in a most irregular manner.

We respectfully submit that a careful consideration of this case will demonstrate that the government was not entitled to the drastic relief which was granted to it below. There is no basis in law or fact for destroying defendants

and an entire industry.

The judgment below should be reversed or appropriately modified.

Respectfully submitted,

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APPENDIX OF STATUTES AND REGULATIONS

§ 553. Rule making

- (a) This section applies, according to the provisions thereof, except to the extent that there is involved—
 - (1) a military or foreign affairs function of the United States; or
 - (2) a matter relating to agency management or personnel or to public property, loans, grants, benefits, or contracts.
- (b) General notice of proposed rule making shall be published in the Federal Register, unless persons subject thereto are named and either personally served or otherwise have actual notice thereof in accordance with law. The notice shall include—
 - (1) a statement of the time, place, and nature of public rule making proceedings:
 - (2) reference to the legal authority under which the rule is proposed; and
 - (3) either the terms or substance of the proposed rule or a description of the subjects and issues involved.

Except when notice or hearing is required by statute, this subsection does not apply—

- (A) to interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice; or
- (B) when the agency for good cause finds (and incorporates the finding and a brief statement of reasons therefor in the rules issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest.
- (c) After notice required by this section, the agency shall give interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments with or without opportunity for oral presentation. After consideration of the relevant matter presented, the agency shall incorporate in the rules adopted a concise general statement of their basis and purpose. When rules are required by statute to be made on the record after opportunity for an agency hearing, sections 556 and 557 of this title apply instead of this subsection.
- (d) The required publication or service of a substantive rule shall be made not less than 30 days before its effective date, except—
 - (1) a substantive rule which grants or recognizes an exemption or relieves a restriction;
 - (2) interpretative rules and statements of policy; or
 - (3) as otherwise provided by the agency for good cause found and published with the rule.
- (e) Each agency shall give an interested person the right to petition for the issuance, amendment, or repeal of a rule.

5 U.S.C. § 702

§ 702. Right of review

A person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action within the meaning of a relevant statute, is entitled to judicial review thereof.

5 U.S.C. §703

§ 703. Form and venue of proceeding

The form of proceeding for judicial review is the special statutory review proceeding relevant to the subject matter in a court specified by statute or, in the absence or inadequacy thereof, any applicable form of legal action, including actions for declaratory judgments or writs of prohibitory or mandatory injunction or habeas corpus, in a court of competent jurisdiction. Except to the extent that prior, adequate, and exclusive opportunity for judicial review is provided by law, agency action is subject to judicial review in civil or criminal proceedings for judicial enforcement.

5 U.S.C. §706

§ 706. Scope of review

To the extent necessary to decision and when presented, the reviewing court shall decide all relevant questions of law, interpret constitutional and statutory provisions, and determine the meaning or applicability of the terms of an agency action. The reviewing court shall—

- (1) compel agency action unlawfully withheld or unreasonably delayed; and
- (2) hold unlawful and set aside agency action, findings, and conclusions found to be—
 - (A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law;
 - (B) contrary to constitutional right, power, privilege, or immunity;
 - (C) in excess of statutory jurisdiction, authority, or limitations, or short of statutory right;
 - (D) without observance of procedure required by law;
 - (E) unsupported by substantial evidence in a case subject to sections 556 and 557 of this title or otherwise reviewed on the record of an agency hearing provided by statute; or
 - (F) unwarranted by the facts to the extent that the facts are subject to trial de novo by the reviewing court.

In making the foregoing determinations, the court shall review the whole record or those parts of it cited by a party, and due account shall be taken of the rule of prejudicial error.

§ 331. Prohibited acts

The following acts and the causing thereof are prohibited:

- (a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded.
- (b) The adulteration or misbranding of any food, drug, device, or cosmetic in interstate commerce.
- (c) The receipt in interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded, and the delivery or prof-fered delivery thereof for pay or otherwise.
- (d) The introduction or delivery for introduction into interstate commerce of any article in violation of section 344 or 355 of this title.
- (e) The refusal to permit access to or copying of any record as required by section 373 of this title; or the failure to establish or maintain any record, or make any report, required under section 355(i) or (j), 357(d) or (g), or 360b(j), (l), or (m) of this title, or the refusal to permit access to or verification or copying of any such required record.
- (f) The refusal to permit entry or inspection as authorized by section 374 of this title.
- (g) The manufacture within any Territory of any food, drug, device, or cosmetic that is adulterated or misbranded.
- (h) The giving of a guaranty or undertaking referred to in section 333(c) (2) of this title which guaranty or undertaking is false, except by a person who relied upon a guaranty or undertaking to the same effect signed by, and containing the name and address of, the person residing in the United States from whom he received in good faith the food, drug, device, or cosmetic; or the giving of a guaranty or undertaking referred to in section 333(c) (3) of this title which guaranty or undertaking is false.
- (i) (1) Forging, counterfeiting, simulating, or falsely representing, or without proper authority using any mark, stamp, tag, label, or other identification device authorized or required by regulations promulgated under the provisions of section 344, 356, 357, or 376 of this title.
- (2) Making, selling, disposing of, or keeping in possession, control, or custody, or concealing any punch, die, plate, stone, or other thing designed to print, imprint, or reproduce the trademark, trade name, or other identifying mark, imprint, or device of another or any like-

ness of any of the foregoing upon any drug or container or labeling thereof so as to render such drug a counterfeit drug.

- (3) The doing of any act which causes a drug to be a counterfeit drug, or the sale or dispensing, or the holding for sale or dispensing, of a counterfeit drug.
- (j) The using by any person to his own advantage, or revealing, other than to the Secretary or officers or employees of the Department, or to the courts when relevant in any judicial proceeding under this chapter, any information acquired under authority of section 344, 348, 355, 356, 357, 360b, 374, or 376 of this title concerning any method or process which as a trade secret is entitled to protection.

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- (k) The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a food, drug, device, or cosmetic, if such act is done while such article is held for sale (whether or not the first sale) after shipment in interstate commerce and results in such article being adulterated or misbranded.
- (1) The using, on the labeling of any drug or in any advertising relating to such drug, of any representation or suggestion that approval of an application with respect to such drug is in effect under section 355 of this title, or that such drug complies with the provisions of such section.
- (m) The sale or offering for sale of colored oleomargarine or colored margarine, or the possession or serving of colored oleomargarine or colored margarine in violation of subsections (b) or (c) of section 347 of this title.
- (n) The using, in labeling, advertising or other sales promotion of any reference to any report or analysis furnished in comparance with section 374 of this title.
- (a) In the case of a prescription drug distributed or offered for sale in interstate commerce, the failure of the manufacturer, packer, or distributor thereof to maintain for transmittal, or to transmit, to any practitioner licensed by applicable State law to administer such drug who makes written request for information as to such drug, true and correct copies of all printed matter which is required to be included in any package in which that drug is distributed or sold, or such other printed matter as is approved by the Secretary. Nothing in this paragraph shall be construed to exempt any person from any labeling requirement imposed by or under other provisions of this chapter.
- (p) The failure to register in accordance with section 360 of this title, the failure to provide any information required by section 360(j) of this title, or the failure to provide a notice required by section 360(j) (2) of this title.

21 U.S.C. §332

§ 332. Injunction proceedings—Jurisdiction of courts

(a) The district courts of the United States and the United States courts of the Territories shall have jurisdiction, for cause shown, and subject to the provisions of section 381 (relating to notice to opposite party) of Title 28, to restrain violations of section 331 of this title, except paragraphs (h)-(j) of said section.

Violation of injunction

(b) In case of violation of an injunction or restraining order issued under this section, which also constitutes a violation of this chapter, trial shall be by the court, or, upon demand of the accused, by a jury. Such trial shall be conducted in accordance with the practice and procedure applicable in the case of proceedings subject to the provisions of section 387 of Title 28.

21 U.S.C. §342(a)

§ 342. Adulterated food

A food shall be deemed to be adulterated-

Poisonous, insanitary, etc., ingredients

(a) (1) If it bears or contains any poisonous or deleterious substan; which may render it injurious to health; but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health; or (2) (A) if it bears or contains any added poisonous or added deleterious substance (other than one which is (i) a pesticide chemical in or on a raw agricultural commodity; (ii) a food additive; (iii) a color additive; or (iv) a new animal drug) which is unsafe within the meaning of section 346 of this title, or (B) if it is a raw agricultural commodity and it bears or contains a pesticide chemical which is unsafe within the meaning of section 346a(a) of this title, or (C) if it is, or it bears or contains, any food additive which is unsafe within the meaning of section 348 of this title: Provided, That where a pesticide chemical has been used in or on a raw agricultural commodity in conformity with an exemption granted or a tolerance prescribed under section 346a of this title and such raw agricultural commodity has been subjected to processing such as canning, cooking, freezing, dehydrating, or milling, the residue of such pesticide chemical remaining in or on such processed food shall, notwithstanding the provisions of sections 346 and 348 of this title, not be deemed unsafe if such residue in or on the raw agricultural commodity has been removed to the extent possible in good manufacturing practice and the concentration of such residue in the processed food when ready to eat is not greater than the tolerance prescribed for the raw agricultural commodity, or (D) if it is, or it bears or contains, a new animal drug (or conversion product thereof) which is unsafe within the meaning of section 360b of this title; or (3) if it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food; or (4) if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health; or (5) if it is, in whole or in part, the product of a diseased animal or of an animal which has died otherwise than by slaughter; or (6) if its container is composed, in whole or in part. of any poisonous or deleterious substance which may render the contents injurious to health; or (7) if it has been in-

tentionally subjected to radiation, unless the use of the radiation was in conformity with a regulation or exemption in effect pursuant to section 348 of this title.

§ 344. Emergency permit control—Conditions on manufacturing, processing, etc., as health measure

(a) Whenever the Secretary finds after investigation that the distribution in interstate commerce of any class of food may, by reason of contamination with micro-organisms during the manufacture, processing, or packing thereof in any locality, be injurious to health, and that such injurious nature cannot be adequately determined after such articles have entered interstate commerce, he then, and in such case only, shall promulgate regulations providing for the issuance, to manufacturers, processors, or packers of such class of food in such locality, of permits to which shall be attached such conditions governing the manufacture, processing, or packing of such class of food, for such temporary period of time, as may be necessary to protect the public health; and after the effective date of such regulations, and during such temporary period, no person shall introduce or deliver for introduction into interstate commerce any such food manufactured, processed, or packed by any such manufacturer, processor, or packer unless such manufacturer, processor, or packer holds a permit issued by the Secretary as provided by such regulations.

Violation of permit; suspension and reinstatement

(b) The Secretary is authorized to suspend immediately upon notice any permit issued under authority of this section if it is found that any of the conditions of the permit have been violated. The holder of a permit so suspended shall be privileged at any time to apply for the reinstatement of such permit, and the Secretary shall, immediately after prompt hearing and an inspection of the establishment, reinstate such permit if it is found that adequate measures have been taken to comply with and maintain the conditions of the permit, as originally issued or as amended.

Inspection of permit-holding establishments

(c) Any officer or employee duly designated by the Secretary shall have access to any factory or establishment, the operator of which holds a permit from the Secretary, for the purpose of ascertaining whether or not the conditions of the permit are being complied with, and denial of access for such inspection shall be ground for suspension of the permit until such access is freely given by the operator.

§ 348. Food additives—Unsafe food additives; exception for conformity with exemption or regulation

- (a) A food additive shall, with respect to any particular use or intended use of such additives, be deemed to be unsafe for the purposes of the application of clause (2) (C) of section 342(a) of this title, unless—
 - (1) it and its use or intended use conform to the terms of an exemption which is in effect pursuant to subsection (i) of this section; or
- (2) there is in effect, and it and its use or intended use are in conformity with, a regulation issued under this section prescribing the conditions under which such additive may be safely used. While such a regulation relating to a food additive is in effect, a food shall not, by reason of bearing or containing such an additive in accordance with the regulation, be considered adulterated within the meaning of clause (1) of section 342(a) of this title.

Petition for regulation prescribing conditions of safe use; contents; description of production methods and controls; samples; notice of regulation

- (b) (1) Any person may, with respect to any intended use of a food additive, file with the Secretary a petition proposing the issuance of a regulation prescribing the conditions under which such additive may be safely used.
- (2) Such petition shall, in addition to any explanatory or supporting data, contain—
 - (A) the name and all pertinent information concerning such food additive, including, where available, its chemical identity and composition:
 - (B) a statement of the conditions of the proposed use of such additive, including all directions, recommendations, and suggestions proposed for the use of such additive, and including specimens of its proposed labeling;
 - (C) all relevant data bearing on the physical or other technical effect such additive is intended to produce, and the quantity of such additive required to produce such effect;
 - (D) a description of practicable methods for determining the quantity of such additive in or on food, and any substance formed in or on food, because of its use; and
 - (E) full reports of investigations made with respect to the safety for use of such additive, including full information as to the methods and controls used in conducting such investigations.
- (3) Upon request of the Secretary, the petitioner shall furnish (or, if the petitioner is not the manufacturer of such additive, the petitioner shall have the manufacturer of such additive furnish, without disclosure to the petitioner) a full description of the methods used in, and the facilities and controls used for, the production of such additive.
- (4) Upon request of the Secretary, the petitioner shall furnish samples of the food additive involved, or articles used as components thereof, and of the food in or on which the additive is proposed to be used.

21 U.S.C. §348

(5) Notice of the regulation proposed by the petitioner shall be published in general terms by the Secretary within thirty days after filing.

Approval or denial of petition; time for issuance of orders; evaluation of data; factors

- (c) (1) The Secretary shall—
 - (A) by order establish a regulation (whether or not in accord with that proposed by the petitioner) prescribing, with respect to one or more proposed uses of the food additive involved, the conditions under which such additive may be safely used (including, but not limited to, specifications as to the particular food or classes of food in or in which such additive may be used, the maximum quantity which may be used or permitted to remain in or on such food, the manner in which such additive may be added to or used in or on such food, and any directions or other labeling or packaging requirements for such additive deemed necessary by him to assure the safety of such use), and shall notify the petitioner of such order and the reasons for such action; or
 - (B) by order deny the petition, and shall notify the petitioner of such order and of the reasons for such action.
- (2) The order required by paragraph (1) (A) or (B) of this subsection shall be issued within ninety days after the date of filing of the petition, except that the Secretary may (prior to such ninetieth day), by written notice to the petitioner, extend such ninety-day period to such time (not more than one hundred and eighty days after the date of filing of the petition) as the Secretary deems necessary to enable him to study and investigate the petition.
- (3) No such regulation shall issue if a fair evaluation of the data before the Secretary—
 - (A) fails to establish that the proposed use of the food additive, under the conditions of use to be specified in the regulation, will be safe: Provided, That no additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal, or if it is found, after tests which are appropriate for the evaluation of the safety of food additives, to induce cancer in man or animal, except that this proviso shall not apply with respect to the use of a substance as an ingredient of feed for animals which are raised for food production, if the Secretary finds (i) that, under the conditions of use and feeding specified in proposed labeling and reasonably certain to be followed in practice, such additive will not adversely affect the animals for which such feed is intended, and (ii) that no residue of the additive will be found (by methods of examination prescribed or approved by the Secre-

tary by regulations, which regulations shall not be subject to subsections (f) and (g) of this section) in any edible portion of such animal after staughter or in any food yielded by or derived from the living animal; or

(B) shows that the proposed use of the additive would promote deception of the consumer in violation of this chapter or would otherwise result in adulteration or in misbranding of food within the meaning of this chapter.

(4) If, in the judgment of the Secretary, based upon a fair evaluation of the data before him, a tolerance limitation is required in order to assure that the proposed use of an additive will be safe, the Secretary—

(A) shall not fix such tolerance limitation at a level higher than he finds to be reasonably required to accomplish the physical or other technical effect for which such additive is intended; and

(B) shall not establish a regulation for such proposed use if he finds upon a fair evaluation of the data before him that such data do not establish that such use would accomplish the intended physical or other technical effect.

(5) In determining, for the purposes of this section, whether a proposed use of a food additive is safe, the Secretary shall consider among other relevant factors—

(A) the probable consumption of the additive and of any substance formed in or on food because of the use of the additive;

(B) the cumulative effect of such additive in the diet of man or animals, taking into account any chemically or pharmacologically related substance or substances in such diet; and

(C) safety factors which in the opinion of experts qualified by scientific training and experience to evaluate the safety of food additives are generally recognized as appropriate for the use of animal experimentation data.

Regulation issued on Secretary's initiative

(d) The Secretary may at any time, upon his own initiative, propose the issuance of a regulation prescribing, with respect to any particular use of a food additive, the conditions under which such additive may be safely used, and the reasons therefor. After the thirtieth day following publication of such a proposal, the Secretary may by order establish a regulation based upon the proposal.

Publication and effective date of orders

(e) Any order, including any regulation established by such order, issued under subsection (c) or (d) of this section, shall be published

and shall be effective upon publication, but the Secretary may stay such effectiveness if, after issuance of such order, a hearing is sought with respect to such order pursuant to subsection (f) of this section.

Objections and public hearing; basis and contents of order; statement

- (f) (1) Within thirty days after publication of an order made pursuant to subsection (c) or (d) of this section, any person adversely affected by such an order may file objections thereto with the Secretary, specifying with particularity the provisions of the order deemed objectionable, stating reasonable grounds therefor, and requesting a public hearing upon such objections. The Secretary shall, after due notice, as promptly as possible hold such public hearing for the purpose of receiving evidence relevant and material to the issues raised by such objections. As soon as practicable after completion of the hearing, the Secretary shall by order act upon such objections and make such order public.
- (2) Such order shall be based upon a fair evaluation of the entire record at such hearing, and shall include a statement setting forth in detail the findings and conclusions upon which the order is based.
- (3) The Secretary shall specify in the order the date on which it shall take effect, except that it shall not be made to take effect prior to the ninetieth day after its publication, unless the Secretary finds that emergency conditions exist necessitating an earlier effective date, in which event the Secretary shall specify in the order his findings as to such conditions.

Judicial review

- (g) (1) In a case of actual controversy as to the validity of any order issued under subsection (f) of this section, including any order thereunder with respect to amendment or repeal of a regulation issued under this section, any person who will be adversely affected by such order may obtain judicial review by filing in the United States Court of Appeals for the circuit wherein such person resides or has his principal place of business, or in the United States Court of Appeals for the District of Columbia Circuit, within sixty days after the entry of such order, a petition praying that the order be set aside in whole or in part.
- (2) A copy of such petition shall be forthwith transmitted by the clerk of the court to the Secretary, or any officer designated by him for that purpose, and thereupon the Secretary shall file in the court the record of the proceedings on which he based his order, as provided in section 2112 of Title 28. Upon the filing of such petition the court shall have jurisdiction, which upon the filing of the record with it shall be exclusive, to affirm or set aside the order complained of in whole or in part. Until the filing of the record the Secretary may

modify or set aside his order. The findings of the Secretary with respect to questions of fact shall be sustained if based upon a fair evaluation of the entire record at such hearing. The court shall advance on the docket and expedite the disposition of all causes filed therein pursuant to this section.

- (3) The court, on such judicial review, shall not sustain the order of the Secretary if he failed to comply with any requirement imposed on him by subsection (f) (2) of this section.
- (4) If application is made to the court for leave to adduce additional evidence, the court may order such additional evidence to be taken before the Secretary and to be adduced upon the hearing in such manner and upon such terms and conditions as to the court may seem proper, if such evidence is material and there were reasonable grounds for failure to adduce such evidence in the proceedings below. The Secretary may modify his findings as to the facts and order by reason of the additional evidence so taken, and shall file with the court such modified findings and order.
- (5) The judgment of the court affirming or setting aside, in whole or in part, any order under this section shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification as provided in section. 1254 of Title 28. The commencement of proceedings under this section shall not, unless specifically ordered by the court to the contrary, operate as a stay of an order.

Amendment or repeal of regulations

(h) The Secretary shall by regulation prescribe the procedure by which regulations under the foregoing provisions of this section may be amended or repealed, and such procedure shall conform to the procedure provided in this section for the promulgation of such regulations.

Exemptions for investigational use

(i) Without regard to subsections (b) to (a), inclusive, of this section, the Secretary shall by regulation provide for exempting from the requirements of this section any food additive, and any food bearing or containing such additive, intended solely for investigational use by qualified experts when in his opinion such exemption is consistent with the public health.

§ 371. Regulations and hearings—Authority to promulgate regulations

(a) The authority to promulgate regulations for the efficient enforcement of this chapter, except as otherwise provided in this section, is vested in the Secretary.

Regulations for imports and exports

(b) The Secretary of the Treasury and the Secretary of Health, Education, and Welfare shall jointly prescribe regulations for the efficient enforcement of the provisions of section 381 of this title, except as otherwise provided therein. Such regulations shall be promulgated in such manner and take effect at such time, after due notice, as the Secretary of Health, Education, and Welfare shall determine.

Conduct of hearings

(c) Hearings authorized or required by this chapter shall be conducted by the Secretary of Health, Education, and Welfare or such officer or employee as he may designate for the purpose.

Effectiveness of definitions and standards of identity

(d) The definitions and standards of identity promulgated in accordance with the provisions of this chapter shall be effective for the purposes of the enforcement of this chapter, notwithstanding such definitions and standards as may be contained in other laws of the United States and regulations promulgated thereunder.

Procedure for establishment

(e) (1) Any action for the issuance, amendment, or repeal of any regulation under section 341, 343(j), 344(a), 346, 351(b), or 352(d) or

(h), of this title shall be begun by a proposal made (A) by the Secretary on his own initiative, or (B) by petition of any interested person, showing reasonable grounds therefor, filed with the Secretary. The Secretary shall publish such proposal and shall afford all interested persons an opportunity to present their views thereon, orally or in writing. As soon as practicable thereafter, the Secretary shall by order act upon such proposal and shall make such order public. Except as provided in paragraph (2) of this subsection, the order shall become effective at such time as may be specified therein, but not prior to the day following the last day on which objections may be filed under such paragraph.

- (2) On or before the thirtieth day after the date on which an order entered under paragraph (1) of this subsection is made public, any person who will be adversely affected by such order if placed in effect may file objections thereto with the Secretary, specifying with particularity the provisions of the order deemed objectionable, stating the grounds therefor, and requesting a public hearing upon such objections. Until final action upon such objections is taken by the Secretary under paragraph (3) of this subsection, the filing of such objections shall operate to stay the effective less of those provisions of the order to which the objections are made. As soon as practicable after the time for filing objections has expired the Secretary shall publish a notice in the Federal Register specifying those parts of the order which have been stayed by the filing of objections and, if no objections have been filed, stating that fact.
- (3) As soon as practicable after such request for a public hearing, the Secretary, after due notice, shall hold such a public hearing for the purpose of receiving evidence relevant and material to the issues raised by such objections. At the hearing, any interested person may be heard in person or by representative. As soon as practicable after completion of the hearing, the Secretary shall by order act upon such objections and make such order public. Such order shall be based only on substantial evidence of record at such hearing and shall set forth, as part of the order, detailed findings of fact on which the order is based. The Secretary shall specify in the order the date on which it shall take effect, except that it shall not be made to take effect prior to the ninetieth day after its publication unless the Secretary finds that emergency conditions exist necessitating an earlier effective date, in which event the Secretary shall specify in the order his findings as to such conditions.

Review of order

(f) (1) In a case of actual controversy as to the validity of any order under subsection (e) of this section, any person who will be adversely affected by such order if placed in effect may at any time

prior to the ninetieth day after such order is issued file a petition with the United States court of appeals for the circuit wherein such person resides or has his principal place of business, for a judicial review of such order. A copy of the petition shall be forthwith transmitted by the clerk of the court to the Secretary or other officer designated by him for that purpose. The Secretary thereupon shall file in the court the record of the proceedings on which the Secretary based his order, as provided in section 2112 of Title 28.

- (2) If the petitioner applies to the court for leave to adduce additional evidence, and shows to the satisfaction of the court that such additional evidence is material and that there were reasonable grounds for the failure to adduce such evidence in the proceeding before the Secretary, the court may order such additional evidence (and evidence in rebuttal thereof) to be taken before the Secretary, and to be adduced upon the hearing, in such manner and upon such terms and conditions as to the court may seem proper. The Secretary may modify his findings as to the facts, or make new findings, by reason of the additional evidence so taken, and he shall file such modified or new findings, and his recommendation, if any, for the modification or setting aside of his original order, with the return of such additional evidence.
- (3) Upon the filing of the petition referred to in paragraph (1) of this subsection, the court shall have jurisdiction to affirm the order, or to set it aside in whole or in part, temporarily or permanently. If the order of the Secretary refuses to issue, amend, or repeal a regulation and such order is not in accordance with law the court shall by its judgment order the Secretary to take action, with respect to such regulation, in accordance with law. The findings of the Secretary as to the facts, if supported by substantial evidence, shall be conclusive.
- (4) The judgment of the court affirming or setting aside, in whole or in part, any such order of the Secretary shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification as provided in sections 346 and 347 of Title 28.
- (5) Any action instituted under this subsection shall survive notwithstanding any change in the person occupying the office of Secretary or any vacancy in such office.
- (6) The remedies provided for in this subsection shall be in addition to and not in substitution for any other remedies provided by law.

Copies of records of hearings

(g) A certified copy of the transcript of the record and proceedings under subsection (e) of this section shall be furnished by the Secretary to any interested party at his request, and payment of the costs thereof, and shall be admissible in any criminal, libel for condemnation, exclusion of imports, or other proceeding arising under or in re-

spect to this chapter, irrespective of whether proceedings with respect to the order have previously been instituted or become final under subsection (f) of this section.

PART 128g--FISH AND SEAFOOD **PRODUCTS**

Subpart A-Smoked and Smoke-Flavored Fish

Definitions.

128a.1 Current good manufacturing practice (sanitation). 128a.2

128a.3 Plants and grounds.

Equipment and utensils. Sanitary facilities and controls. 128a.5

Sanitary operations. 1288.6

128a.7 Processes and controls.

Subparts B-D-[Reserved]

Subpart E-Frazen Raw Breaded Shrimp

128a.401 Definitions. 128a.402 Current good manufacturing practice (sanitation).

128a.403 Plants and grounds.

Equipment and utensils. 1289 404 128a.405 Sanitary facilities and controls.

128a.406 Sanitary operations. 128a.407 Processes and controls.

AUTHORITY: The provisions of this Part 128a issued under secs. 402(a)(4), 701(a). 52 Stat. 1046, 1055; 21 U.S.C. 342(a)(4). 371(a).

Subpart A-Smoked and Smoke-Flavored Fish

Source: The provisions of this Subpart A ppear at 35 F.R. 17401, Nov. 13, 1970, 35 F.R. 17840, Nov. 20, 1970, unless otherwise noted

§ 128a.1 Definitions.

(a) Smoked fish. As used in this part. the term "smoked fish" means any fish that is prepared by treating it with salt (sodium chloride) and then subjecting it to the direct action of smoke from burning wood, sawdust, or similar material

(b) Smoke-flavored fish. As used in this part, the term "smoke-flavored fish" means any fish that is prepared by treating it with salt (sodium chloride) and then imparting to it the flavor of smoke by other than the direct action of smoke This paragraph does not-alter the labeling requirements under § 1.12 of this chapter.

(c) Loin muscle. As used in this part, "loin muscle" means the longitudinal quarter of the great lateral muscle freed from skin, scales, visible blood clots. bones, gills, and viscera and from the nonstriated part of such muscle, which part is known anatomically as the me-

dian superficial muscle.

(d) Water phase salt. As used in this part, "Water phase salt" means the percent sait (sodium chloride) in the finished product as determined by the method described in sections 18.009 and 18.010 of the "Official Methods of Analysis of the Association of Agricultural Chemists," 10th edition, page 273 (1965). multiplied by 100 and divided by the percent sait (sodium chloride) plus the percent moisture in the finished product as determined by the method described in section 18.006 of said edition.

(e) Hot-process smoked or hot-process smoke-flavored fish. As used in this part "hot-process smoked or hot-process smoke-flavored fish" means the finished food prepared by subjecting forms of smoked fish referred to in paragraphs

(a) and (b) of this section to heat as prescribed in § 128a.7(d).

[35 FR 17401, Nov. 13, 1970; 35 FR 17840. Nov. 20, 1970, as amended at 39 FR 9828. Mar. 14, 1974]

§ 128a.2 Current good manufacturing practice (sanitation).

- (a) The criteria in Part 128 of this chapter shall apply in determining whether the facilities, methods, practices, and controls used for the manufacture, processing, packing, or holding of fish and seafood products are in conformance with and are operated or administered in conformity with good manufacturing practice to produce, under sanitary conditions, food for human consumption.
- (b) The criteria in this Subpart A set forth additional requirements for the hot-process smoked or hot-process smoke-flavored fish industry.

§ 128a.3 Plants and grounds.

- (a) Unloading platforms shall be:
- (1) Made of readily cleanable material.
- (2) Equipped with drainage facilities adequate to accommodate all seepage and wash water.
- (b) The following processes should be carried out in separate rooms or facilities, and the interior walls separating these processes should extend from floor to ceiling and contain only necessary openings (such as for conveyors and door ways) :
 - (1) Receiving or shipping.
 - (2) Storage of raw fish.
- (3) Presmoking operations (thawing, dressing, brining, etc.).
 - (4) Drying and smoking.
- (c) The following processes shall be carried out in separate rooms or facilities, and the interior walls separating these processes shall extend from floor to ceiling and contain only necessary openings (such as for conveyors and doorways):
 - (1) Cooling and packing.
 - (2) Storage of final product.
- (d) The product shall be so processed as to prevent contamination by exposure to areas, utensils, or equipment, involved in earlier processing steps, refuse, or other objectionable areas.

*§ 128a.4 Equipment and utensils.

- (a) All food-contact surfaces (tanks, belts, tables, utensils, and other equip-ment) shall be made of readily cleanable materials.
- (b) Metal seams shall be smoothly soldered, welded, or bonded.
- (c) Each freezer and cold storage compartment used for the product shall be fitted with at least the following:
- (1) An automatic control for regulating temperature.
- (2) An indicating thermometer so installed as to show accurately the temperature within the compartment.
- (3) A recording thermometer so installed as to indicate accurately at all times the temperature within the compartment.

(d) Thermometers or other temperature-measuring devices shall have an accuracy of $\pm 2^{\circ}$ F.

§ 128a.5 Sanitary facilities and controls.

(a) Adequate hand-washing and sanitizing facilities shall be located in the processing room(s) or in one area easily accessible from the processing room(s).

(b) Readily understandable signs directing employees to wash and sanitize their hands after each absence from post of duty shall be conspicuously posted in the processing room(s) and elsewhere in the plant as conditions require.

(c) Offal shall be placed in suitable covered containers for removal at least once a day, or more frequently if necessary, or shall be removed by conveyors or chutes. Offal, debris, or refuse from any source whatever shall not be allowed to accumulate in or about the plant.

§ 128a.6 Sanitary operations.

- (a) Before beginning the day's operation, all utensils and product-contact surfaces of equipment to be used for the day's operation shall be rinsed and sanitized.
- (b) Containers used to convey or store sh shall not be nested while they contain fish or otherwise handled during processing or storage in a manner contactive to direct or indirect contamination of their contents.
- (c) Cleaning and sanitizing of utensils and portable equipment should be conducted in an area set aside for these purposes and shall be carried out in such a manner as to prevent contamination of the fish or fish products.

§ 128a.7 Processes and controls.

(a) Raw materials. (1) Presh fish received shall be inspected and adequately washed before processing. Only sound, wholesome fish free from adulteration and organoleptically detectable spoliage shall be processed.

(2) Every lot of fish that has been partially processed in another plant, including frozen fish, shall be adequately inspected, and only clean, wholesome fish

shall be processed.

(3) Fresh or partially processed fish, except those to be immediately processed, shall be iced or otherwise refrigerated to an internal temperature of 35° F. or below upon receipt and shall be maintained at that temperature until the fish are to be processed.

(4) All fish received in a frozen state shall be either thawed promptly and processed, or stored at a temperature that will maintain it in a frozen state.

(b) Defrosting of frozen fish. (1) Defrosting shall be carried out in a sanitary manner and by such methods that the wholesomeness of the fish is not adversely affected. Frozen fish shall be defrosted:

(i) In air at 45° F, or below until other

than hard frozen; or

(ii) In air so that the temperature in any part of the fish does not exceed 45°F.; or

(iii) In a continuous water-overflow thaw tank or spray system in such a manner that the temperature in any part of the fish does not exceed 45° F.

(2) When a thaw tank is used, fish should not remain in the tank longer than one-half hour after they are completely defrosted.

(3) Fish entering the thaw tanks shall be free of exterior packaging material and substantially free of liner material.

(4) After thawing, fish shall be washed thoroughly with a vigorous water spray or a continuous waterflow system.

(c) Presmoking operation. (1) Evisceration of fish shall be performed with minimum disturbance of intestinal tract contents. Removal of viscera shall be complete.

(2) After the evisceration process, the fish (including the body cavity) shall be thoroughly washed with a vigorous water spray or a continuous waterflow system.

(3) All fish shall be dry-salted at a temperature not to exceed 38° F through-

out the fish, or shall be brined in such a manner that the temperature of the fish and the brine:

(i) Does not exceed 60° F at the start

of brining, and

(ii) If between 38° F and 50° F at the start of brining, is continuously lowered to 38° F or below within 12 hours, and

(iii) If between 50° F and 60° F at the start of brining, is continuously lowered to 50° F or below within 2 hours and to 38° F or below within the following 10 hours, and

(iv) Does not rise above 38° F after reaching that temperature or below either prior to or during the brining

operation.

(4) Hot-process smoked or hot-process smoke-flavored fish shall be brined in such a maner that the final salt (sodium chloride) content of the loin muscle of the finished product, expressed as percent in the water phase of the loin muscle, shall not be less than:

(i) 3.5 percent if heat-processed as prescribed under paragraph (d) (2) (i) of

this section; or

(ii) 5.0 percent if heat-processed as prescribed under paragraph (d) (2) (ii) of this section.

(5) Fish shall be rinsed with fresh

water after brining.

(d) Heating, cooking, smoking operation. (1) A point-sensitive, continuous temperature-recording device shall be used to monitor both the internal temperature of the fish and the ambient temperature within the oven. Each recording-device record shall be identified as to the specific oven load and date processed.

(2) Hot-process smoked or hot-process smoke-flavored fish shall be heated by a controlled hast process that provides a monitoring system positioned in as many strategic locations in the oven as necessary to assure a continuous temperature throughout each fish of:

(i) Not less than 180° F. for a minimum of 30 minutes for hot-process smoked or hot-process smoke-flavored fish which have been brined to contain 3.5 percent water phase salt in the finished product as prescribed in paragraph (c) (4) (i) of this section, except that smoked chub containing sodium nitrite as provided for in § 121.1230 of this chapter shall be processed in accordance with that section; or

(ii) Not less than 150° F. for a minimum of 30 minutes for hot-process smoked or hot-process smoke-flavored fish which have been brined to contain 5.0 percent water phase salt in the finished product as prescribed in paragraph (c) (4) (ii) of this section.

(e) Packing. (1) The finished product shall be handled only with clean, sani-

tized hands, gloves, or utensils.

(2) Manual manipulation of the finished product shall be kept to a minimum.

(3) The finished product shall be cooled to a temperature of 50° F. or below within 3 hours after cooking and further cooled to a temperature of 38° F. or below within 12 hours after cooking, and this temperature shall be maintained during all subsequent storage and distribution.

(4) The shipping containers, retail packages, and shipping records shall indicate by appropriate labeling the perishable nature of the product and shall specify that the product shall be shipped, stored, and/or held for sale at 38° F.

or below until consumed.

(5) Permanently legible code marks shall be placed on the outer layer of every finished product package and master carton. Such marks shall identify at least the plant where packed, the date of packing, and the oven load. Records shall be so maintained as to provide positive identification (i) of the process procedures used for the manufacture of hot-process smoked or hot-process smoke-flavored fish and (ii) of the distribution of the finished product.

(f) Testing. (1) Microbiological examination of in-line and finished product samples should be conducted with sufficient frequency to assure that processing steps and sanitary procedures are

adequate.

(2) The finished product shall be analyzed chemically with sufficient frequency to assure that the required salinity is obtained in every fish and that other chemical additives are present at authorized levels.

[35 FR 17401, Nov. 13, 1970, as amended at 38 FR 13481, May 22, 1973]

STATE OF NEW YORK) COUNTY OF NEW YORK) ss.:

ADOLF MAY, being duly sworn,
ADOLF MA, being duly sworn, deposes and says that deponent is not a party to the action, is over 18 years of age and resides at 44 BENNETT ALE
WEST YORK, N.Y. 10033.
That on the 30 day of DECEMBER, 1976, deponent personally served the within BRIEF OF APPELLANTS
upon the attorneys designated below who represent the indicated parties in this action and at the addresses below stated which are those that have been designated by said attorneys for that purpose.
By leaving 2 true copies of same with a duly authorized person at their designated office.
By depositing true copies of same enclosed in a postpaid properly addressed wrapper, in the post office or official depository under the exclusive care and custody of the United Stated post office department within the State of New York.
Names of attorneys served, together with the names of the clients represented and the attorneys' designated addresses.
DAVID TRAGER ESO. UNITED STATES ATTORNEY FOR THE EASTERN DISTRICT OF LIEW YORK ATTORNEY FOR PLAINTIFF APPELLED 225 CADMAN PLAZA EAST
BROOKLYN, N.Y. 11201
Jovep More
day of Velender, 1976 Weeker De Sente
MICHAEL DESANTS Notary Public, State of New York No. 03-0930908 Qualified in Bronx County Qualified in Bronx County Commission Expires March 30, 1938